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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| IN RE HUMANIGEN, INC. SECURITIES LITIGATION | Case No. 2:22-cv-05258-WJM-AME<br><br>**CLASS ACTION** |
| THIS DOCUMENT RELATES TO:<br><br>CONSOLIDATED ACTION | **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**<br><br>**JURY TRIAL DEMANDED** |

Co-Lead Plaintiffs Dr. Scott Greenbaum and Joshua Mailey together with Plaintiff Alejandro Pieroni (collectively, "Plaintiffs"), individually and on behalf of all others similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants, allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Humanigen, Inc. ("Humanigen"), analysts' reports and advisories about Humanigen, and information readily obtainable on the Internet. Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Humanigen securities between May 16, 2020 and July 12, 2022, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of

the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against Humanigen and certain of its top officials.

2. Humanigen was formerly known as KaloBios Pharmaceuticals, Inc. and run by convicted fraudster Martin "Pharma Bro" Shkreli along with Defendants Cameron Durrant and Dale Chappell. In 2015, following Shkreli's arrest, the company entered bankruptcy and began a restructuring process that ultimately concluded in 2017 with Durrant and Chappell at the helm of the company under its new name, Humanigen. Durrant was Humanigen's CEO and Chappell, having loaned the company over $18 million by this point in time, had become its controlling shareholder. Despite their efforts to right the company, Humanigen's outlook was bleak. As of December 31, 2019, Humanigen did not have enough capital to fund operations for the next year and, as a result, its auditors had expressed "substantial doubt" about the company's "ability to continue as a going concern."

3. Then COVID happened. For much of the world, the pandemic brought extreme sadness and difficulty as communities changed their lives to stop the spread of the virus. For Defendants though, the pandemic created an unexpected, lucrative opportunity. Historically, Humanigen's primary objective had always been to develop its lead drug candidate, lenzilumab, for use as a cancer treatment. When COVID happened, Defendants announced that their drug could be repurposed for use as a COVID treatment and, within a matter of days, reorganized Humanigen's entire

clinical development program.

4. Defendants' statements about lenzilumab's use as a COVID treatment were false and materially misleading. As previously mentioned, lenzilumab was historically intended to be used as a cancer treatment. More specifically, lenzilumab was intended to treat a specific side-effect known as "cytokine release syndrome" or "cytokine storm" that patients sometimes experienced when receiving chemotherapy. Cytokine storm is triggered by the production of "granulocyte-macrophage colony-stimulating factor" or GM-CSF. Lenzilumab was designed to block or inhibit the production of GM-CSF which, in turn, would prevent cytokine release syndrome.

5. Once COVID emerged, Defendants told investors that "recent data from China" and certain "pre-publication" papers supported the "scientific rationale" for lenzilumab's use in the treatment of COVID patients. Absent from Defendants' public statements, however, was any mention of the fact that GM-CSF was necessary for healthy and normal lung function. Academic literature and medical publications had demonstrated that GM-CSF is required for lung alveoli to work properly and facilitate the exchange between oxygen and carbon dioxide in the lungs. Thus, contrary to Defendants' statements, lenzilumab presented a specific and acute risk if given to COVID patients who were already experiencing lung dysfunction. Defendants concealed this risk from the public and proceeded in hopes of obtaining an Emergency Use Application, or EUA, from the FDA that would allow Humanigen to

commercialize its historical lead drug candidate and save the company from financial collapse.

6. Throughout the Class Period, Defendants repeatedly promoted lenzilumab's prospects as a successful COVID treatment while, at the same time, raising over $300 million through public offerings that allowed Humanigen to avert insolvency. Further, Chappell and Durrant also engaged in numerous insider stock sales, with Chappell in particular selling over $65 million of Humanigen shares.

7. Defendants would have profited even more had the FDA not decided to reject Humanigen's application for an EUA. On September 9, 2021, Humanigen issued a press release announcing that the FDA had rejected the lenzilumab EUA, advising investors that, "[i]n its letter, [the] FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19." On this news, Humanigen's stock price fell $7.14 per share, or 47.25%, to close at $7.97 per share on September 9, 2021.

8. Despite this, Defendants continued to mislead investors by reiterating the "scientific rationale" of using lenzilumab to treat COVID and Humanigen's prospects of securing approval upon submitting additional data from an ongoing clinical trial being conducted by the National Institute of Health referred to as the ACTIV-5/BET- B study. Contrary to these claims, on July 13, 2022, Humanigen disclosed that lenzilumab had failed to show statistical significance on the primary

endpoint of the ACTIV-5/BET- B study. On this news, Humanigen's stock price fell $2.38 per share, or 79.6%, to close at $0.61 per share on July 13, 2022.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Humanigen's securities, Plaintiffs and other Class members have suffered significant losses and damages.

## JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Humanigen is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## PARTIES

14. Plaintiff Dr. Greenbaum, as set forth in his previously filed Certification, acquired Humanigen securities at artificially inflated prices during the Class Period and was damaged as a result. *See* Dkt. No. 7-3.

15. Plaintiff Mailey, as set forth in his previously filed Certification, acquired Humanigen securities at artificially inflated prices during the Class Period and was damaged as a result. *See* Dkt. No. 9-3.

16. Plaintiff Pieroni, as set forth in the attached Certification, acquired Humanigen securities at artificially inflated prices during the Class Period and was damaged as a result.

17. Defendant Humanigen is a Delaware corporation with principal executive offices located at 830 Morris Turnpike, 4th Floor, Short Hills, New Jersey 07078. Humanigen's common stock trades on the Nasdaq Stock Market ("NASDAQ") under the trading symbol "HGEN". Prior to trading on the NASDAQ, Humanigen's common stock traded on the OTCQB Venture Market ("OTCBQ") operated by OTC Market's Group, Inc. under the symbol "HGEND". At all relevant times, Humanigen's common stock traded in an efficient market.

18. Defendant Cameron Durrant ("Durrant") has served as Humanigen's Chairman and Chief Executive Officer at all relevant times.

19. Defendant Dale Chappell ("Chappell") has served as Humanigen's Chief

Scientific Officer and a member of Humanigen's Board of Directors at all relevant times. During the Class Period, Chappell was Humanigen's largest shareholder through his control of the Black Horse Entities (defined below).

20. Relevant non-parties Black Horse Capital Master Fund Ltd. ("BHCMF"), Black Horse Capital L.P. ("BHC"), and Cheval Holdings, Ltd. (collectively, the "Black Horse Entities") owned and/or controlled the majority of Humanigen's stock between February 27, 2018 and June 2, 2020. After June 2, 2020, the Black Horse Entities owned and/or controlled between 18% and 33% of Humanigen's stock and was at all relevant times the largest shareholder of the company. Chappell owned and/or controlled the Black Horse Entities at all relevant times. Through Chappell, the Black Horse Entities had access to a significant amount of material non-public information and had the ability to control Humanigen's day-to-day operations.

21. Defendants Durrant and Chappell are sometimes referred to herein as the "Individual Defendants."

22. Humanigen and the Individual Defendants are collectively referred to herein as "Defendants."

## SUBSTANTIVE ALLEGATIONS

### Background

23. Humanigen was previously known as KaloBios Pharmaceuticals, Inc.

and run by the convicted securities fraudster Martin Shkreli known as "Pharma Bro". In December 2015, the company filed for bankruptcy and, in August 2017, changed its name to Humanigen.

24. Following the restructuring, Humanigen operated as a clinical-stage biopharmaceutical company focused on developing treatments against negative side-effects associated with cancer treatments, including an immunotherapy treatment known as chimeric antigen receptor T-cell therapy or CAR-T therapy.

25. Lenzilumab was Humanigen's lead product candidate. Prior to COVID, Humanigen described lenzilumab as a novel monoclonal antibody (a man-made protein to help immune systems) that had the "potential to both improve the efficacy and safety associated with CAR-T therapy." According to Humanigen, preclinical data from the Mayo Clinic suggested that lenzilumab could prevent the onset of CAR-T side-effects, including neurologic toxicities and conditions known as "cytokine release syndrome" or "cytokine storm." Cytokine release syndrome is an acute systemic inflammatory syndrome that can lead to organ failure or death.

26. CAR-T therapies caused patients to experience a rise in levels of a cytokine (a kind of protein) known as a granulocyte-macrophage colony-stimulating factor or GM-CSF. GM-CSF, according to Humanigen, was closely related to neurologic toxicities and cytokine release syndrome. Lenzilumab worked to prevent these side-effects by targeting and neutralizing GM-CSF, thereby stopping the onset

of neurologic toxicity and/or cytokine release syndrome.

27. Humanigen sought to develop lenzilumab through clinical trials with the objective of having it used in connection with CAR-T therapy. To this end, Humanigen attempted to partner with CAR-T therapy centers and companies to conduct testing. As Humanigen explained, the company "aim[ed] to position lenzilumab as a 'must have' companion product to any CAR-T therapy and an essential part of the standard pre-conditioning that all patients administered CAR-T must receive."

28. During 2019 and throughout the early portion of the first quarter of 2020, Humanigen pursued its anti-GM-CSF programs for use with CAR-T therapies. Specifically, in collaboration with Kite Pharmaceuticals, Inc. (which was owned by Gilead Sciences, Inc.), Humanigen was studying the effect of lenzilumab on the safety of Kite Pharmaceuticals' FDA-approved CAR-T therapy, Yescarta. Humanigen sought to conduct a multi-center study to measure the effect of lenzilumab in reducing cytokine storm and neurotoxicity with a secondary endpoint of increased efficacy of Yescarta.

29. While Humanigen projected a growing "CAR-T market," there were only two approved CAR-T therapies as of 2019 (one of which was Yescarta). Moreover, both therapies had "black box warnings" for cytokine release syndrome and neurologic toxicities. "Black box warnings" are required by the FDA to notify

patients about severe safety-related risks. Thus, the use of these CAR-T therapies and, in turn, the potential for lenzilumab's use were significantly limited. Reimbursement challenges for these CAR-T therapies further limited their use and, in turn, the potential for prescribing lenzilumab.

30. By 2019, Humanigen's prospects for success were dwindling. Its "development program" for lenzilumab had been unsuccessful financially both prior to and after its restructuring in bankruptcy. In fact, as of December 31, 2019, Humanigen had "substantial doubt[s] about [its] ability to continue as a going concern" due, in part, to its accumulated deficit of nearly $285 million and foreseeable net losses going forward. As of December 31, 2019, Humanigen's cash and cash equivalents totaled only $100 thousand.

31. Humanigen's ability to survive up until this point was in large part due to financing received from Chappell and the Black Horse Entities. As of February 2018, Chappell and the Black Horse Entities had extended Humanigen approximately $18.4 million, which had been provided over the previous years under various credit and loan agreements. Instead of repaying the $18.4 million, Humanigen issued Chappell and the Black Horse Entities over 66.8 million shares of common stock. At the time, these shares represented approximately 62.6% of Humanigen's outstanding common stock, thereby leaving Chappell (who owned and/or controlled the Black Horse Entities) as the company's controlling shareholder.

## COVID-19

32. The COVID-19 pandemic erupted in early-2020. For much of the world, it caused extreme difficulty and sadness as people sought to stop the spread of the virus and insulate their communities and loved ones from exposure. For Defendants, the pandemic presented a chance to break away from what appeared to be a growingly dim business plan and take advantage of an unexpected opportunity.

33. In March 2020, Humanigen began telling investors that lenzilumab could potentially be repurposed for use in COVID patients who experienced severe cases of lung dysfunction. According to Humanigen, COVID patients were dying from lung dysfunction caused by cytokine release syndrome or cytokine storm. These patients had elevated levels of GM-CSF, which was the cytokine that lenzilumab was designed to target and neutralize in the context of CAR-T therapy treatment.

34. Humanigen immediately changed its business plan to include lenzilumab as a potential treatment against cytokine storm in COVID patients. Humanigen implemented this change in its plan even though there was no proof to support the claim that elevated GM-CSF levels were contributing to cytokine storm outbreaks in COVID patients. Indeed, according to Humanigen, its change in strategy was supported by "[r]ecent data from China" and an unpublished paper that had not been peer-reviewed or substantiated.

35. To the contrary and absent from Humanigen's filings with the SEC at this time, GM-CSF played an important role in improving the health of patients with

respiratory diseases, including the lung dysfunction experienced by COVID patients.

36. The lungs contain alveoli. Alveoli are tiny sacs within the lungs where oxygen is exchanged for carbon dioxide in the blood. They are integral to the breathing process.

37. GM-CSF plays a critical role with respect to alveoli. It is responsible for maintaining the alveolar epithelium and pulmonary immune system and ensures homeostasis when under attack, *e.g.*, infection. In response to disease, the body creates GM-CSF which, in turn, drives the recovery process within the alveoli and the lungs. When GM-CSF is suppressed, this recovery process is inhibited, and patient health is at risk of deteriorating.

38. Numerous studies have demonstrated the positive effects of administering (as opposed to inhibiting) GM-CSF when treating for lung dysfunction. These studies both pre- and post-date the Class Period. For example:

a. GM-CSF in mice prevented lung injury by strengthening alveolar cells and protecting against bacterial infection[1];

b. GM-CSF in patients with acute lung injury correlated with increased survival[2];

[1] Baleeiro CE, *et al*. GM-CSF and the impaired pulmonary innate immune response following hyperoxic stress. Am. J. Physiol. Lung Cell Mol. Physiol. 2006; Paine R, III, *et al*. Transgenic overexpression of granulocyte macrophage-colony stimulating factor in the lung prevents hyperoxic lung injury. Am. J. Pathol. 2003.

[2] Matute-Bello G, *et al*. Modulation of neutrophil apoptosis by granulocyte colony-stimulating factor and granulocyte/macrophage colony-stimulating factor during the course of acute respiratory distress syndrome. Crit. Care Med. 2000.

c. GM-CSF in the lung demonstrated benefits against viral and bacterial pneumonia by increasing repair of injured lung tissue and activating immune responses to clear pathogens[3];

d. Pretreatment with GM-CSF protected mice from lethal influenza-induced lung injury[4];

e. GM-CSF after influenza viral infection in mice significantly increased survival[5];

f. Inhaled GM-CSF protected against secondary bacterial infection in a post-influenza pneumonia mouse models[6];

g. Conversely, GM-CSF-deficient mice demonstrated lack of survival due to impaired alveolar function[7];

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[3] Rosler B, *et ano.*, Lung epithelial GM-CSF improves host defense function and epithelial repair in influenza virus pneumonia-a new therapeutic strategy? *Mol. Cell Pediatr.* 2016; Standiford LR, *et al*. TLR4-dependent GM-CSF protects against lung injury in Gram-negative bacterial pneumonia. *Am. J. Physiol. Lung Cell Mol. Physiol.* 2012; Unkel B, *et al*. Alveolar epithelial cells orchestrate DC function in murine viral pneumonia. J. Clin. Invest. 2012; Sever-Chroneos Z, *et al*. GM-CSF modulates pulmonary resistance to influenza A infection. *Antivir. Res.* 2011; Steinwede K, *et al*. Local delivery of GM-CSF protects mice from lethal pneumococcal pneumonia. *J. Immunol.* 2011.

[4] Subramaniam R, *et al*. Delivery of GM-CSF to protect against influenza pneumonia. *PLoS One.* 2015; Huang H, *et al*., Protective effects of recombinant human granulocyte macrophage colony stimulating factor on H1N1 influenza virus-induced pneumonia in mice. *Cytokine.* 2010.

[5] Halstead ES, *et al*. GM-CSF overexpression after influenza a virus infection prevents mortality and moderates M1-like airway monocyte/macrophage polarization. *Respir. Res.* 2018.

[6] Umstead TM, et al. Lower respiratory tract delivery, airway clearance, and preclinical efficacy of inhaled GM-CSF in a postinfluenza pneumococcal pneumonia model. *Am. J. Physiol. Lung Cell Mol. Physiol.* 2020.

[7] Ballinger MN, *et al*. Role of granulocyte macrophage colony-stimulating factor during gram-negative lung infection with Pseudomonas aeruginosa. *Am. J. Respir. Cell Mol. Biol.* 2006.

h. During infection recovery, GM-CSF stimulated alveolar epithelial cell growth and repair[8];

i. In six patients with pneumonia-associated acute respiratory distress syndrome (compared to a control group), increased oxygenation was observed following treatment with inhaled GM-CSF[9]; and

j. Partner Therapeutics, Inc. conducted and completed a clinical trial showing that GM-CSF in hospitalized COVID patients suffering from respiratory failure resulted in improved oxygenation after five days of treatment compared to standard of care treatment. Top-line data showed that the treatment was well-tolerated with no incidences of cytokine storm[10].

39. Given its crucial role in normal lung health and immune responses, inhibiting and/or neutralizing GM-CSF presented a material (and, as alleged below, undisclosed) risk with respect to lenzilumab's overall clinical benefit among COVID patients with lung dysfunction. Specifically, as supported by academic literature and clinical studies, GM-CSF historically played a critical role in maintaining normal lung function, *i.e.*, homeostasis. Therefore, blocking or inhibiting GM-CSF created the risk

[8] Cakarova L, *et al*. Macrophage tumor necrosis factor-alpha induces epithelial expression of granulocyte-macrophage colony-stimulating factor: impact on alveolar epithelial repair. *Am. J. Respir. Crit. Care Med.* 2009; Huffman Reed JA, *et al*. GM-CSF enhances lung growth and causes alveolar type II epithelial cell hyperplasia in transgenic mice. *Am. J. Physiol.* 1997.

[9] Herold S, *et al*. Inhaled granulocyte/macrophage colony-stimulating factor as treatment of pneumonia-associated acute respiratory distress syndrome. Am. J. Respir. Crit. Care Med. 2014

[10] Partner Therapeutics, *SARPAC Clinical Trial of Leukine® (sargramostim, rhu GM-CSF) in Hospitalized COVID-19 Patients Meets Primary Endpoint of Significant Improvement in Lung Function* (Feb. 26, 2021).

of compromising or destroying alveolar function and preventing patient lungs from clearing pathogens or other disease-related conditions.

**LIVE-AIR Clinical Trial**

40. Federal law requires pharmaceutical companies to obtain permission from the FDA before marketing a drug to the public and, in turn, generating revenue from sales. To obtain permission, a company (or sponsor) must demonstrate that the drug is safe, effective, and that its benefits outweigh its risks. This is typically done through clinical trials and the submission of a New Drug Application (NDA) or Biologics License Application (BLA). All drugs currently marketed within the United States were, at some point, the subject of an approved NDA or BLA.

41. A properly submitted NDA or BLA provides the FDA with all pertinent information about the drug, including data and statistical analyses sufficient to determine whether: (1) the drug is safe and provides the benefits it purports to; (2) the benefits of the drug outweigh its risks; (3) the drug's proposed labeling is appropriate and what it should contain; and (4) the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. Although safety and efficacy are particularly important in the FDA's assessment, each of these issues is independently critical to the agency's ultimate approval decision.

42. In order to meet these standards, drug developers typically subject a drug

candidate to a series of clinical trials designed to accumulate the data required to submit a successful NDA or BLA. Phase 1 clinical trials typically evaluate an investigational drug's safety and dosage tolerance. Phase 2 clinical trials: (1) usually involve larger patient populations; (2) evaluate dosage tolerance and appropriate dosage; (3) identify possible short-term adverse effects and safety risks; and (4) provide a preliminary evaluation of the efficacy of the drug for specific indications. Finally, Phase 3 clinical trials test for efficacy and safety in an even further expanded patient population. Phase 3 trials also usually involve comparison with placebos and are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling.

43. In addition to the above process, a company can obtain an Emergency Use Authorization ("EUA") for its drug under exigent circumstances. Similar to the standard for approval associated with an NDA, the standard for granting an EUA is whether, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective and that the potential benefits outweigh the potential risks.

44. On May 5, 2020, Humanigen bypassed the majority of the traditional clinical trial process laid out above and commenced a Phase 3 study to test lenzilumab in COVID patients. The study, referred to as the "LIVE-AIR trial," was a multicenter, randomized, placebo-controlled, double-blinded clinical trial. Patients with severe

COVID symptoms received three intravenous doses of lenzilumab (600 mg per dose) or placebo delivered eight hours apart. The primary endpoint was survival without ventilation.

45. Humanigen intended to use the results of the LIVE-AIR trial as its sole support for an EUA from the FDA. If approved, Humanigen would have been able to market lenzilumab for use in hospitalized COVID patients. Humanigen estimated a commercial launch date in the fourth quarter of 2020 followed by an expanded product launch within six months. The possibility of an EUA for lenzilumab presented a dire opportunity for the company to generate revenue.

**ACTIV-5/BET Study**

46. On July 24, 2020, while the LIVE-AIR study was underway, Humanigen entered into a clinical trial agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), a division within the National Institute of Health. Pursuant to the agreement, the NIAID agreed to evaluate lenzilumab in hospitalized COVID patients in its Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)-5 and Big Effect Trial, referred to as "ACTIV-5/BET."

47. The purpose of the ACTIV-5/BET was to identify potential treatments that could be used in COVID patients and advance those that showed promise into larger clinical trials. The study was expected to enroll participants across 40 testing sites within the United States and test lenzilumab with other COVID treatments, including remdesivir, against various standards of care. Regarding lenzilumab,

hospitalized COVID patients would receive the drug with remdesivir, compared to a placebo and remdesivir, with approximately 100 patients expected to be assigned to each study arm.

**Humanigen's Type B Meeting with the FDA**

48. On October 2, 2020, Humanigen announced that it had participated in a Type B meeting with the FDA. Type B meetings are milestone meetings that the FDA holds with sponsors (biopharmaceutical companies) to discuss the overall development program for products in development, such as Humanigen's lenzilumab.

49. With respect to lenzilumab, the press release stated that the "FDA agreed that the Company's intended submission may be sufficient to support an EUA request, subject to Phase 3 [LIVE-AIR] trial data, and provided guidance and support for the Company's Biologics License Application approval pathway."

50. The press release also quoted Durrant, stating that the "FDA was very helpful and provided clear guidance on our EUA submission plan. . . . We are encouraged by our Type B meeting and remain confident in our program and preparedness plan in advance of a potential EUA."

**Phase 3 Data Announcement**

51. On November 6, 2020, Humanigen announced positive interim Phase 3 data from the LIVE-AIR study. According to Humanigen, "the interim analysis for sizing and powering suggested that Lenzilumab had a clinically meaningful impact

on patient recovery, with an estimated 37 percent more recoveries observed in the lenzilumab arm of the randomized, placebo-controlled, double-blinded study versus current standard of care (SOC)."

52. Humanigen also stated that it would be increasing the size of the trial from 300 to 515 patients to maintain 90% power based on recommendations of the independent Data and Safety Monitoring Board ("DSMB"). According to the press release, the DSMB "conducted an interim analysis of the unblinded data for trial sizing and powering and recommended increasing the target number of events (recoveries) . . . to maintain the power of the study at 90 percent. The adaptive trial design only allows for the addition of patients if interim data are in the 'promising zone' (i.e., achieving or surpassing an average improvement in recoveries of 29 percent (hazard ratio (HR) $\geq$ 1.29 through day 28)."

53. Humanigen also stated that, "[a]t the recommendation of the DSMB, the company plans to increase enrollment to achieve 402 events (approximately 515 patients). This increase in enrollment ensures an even higher probability of success in meeting the primary endpoint and maintains the power of the study at 90 percent."

54. Humanigen further stated that it intended "to file for EUA in the first quarter of 2021 either following interim data at 75 percent or at study completion. The Phase 3 trial . . . is enrolling at sites across the U.S. and Latin America. Current enrollment stands at 300."

55. The following month, on December 31, 2020, Humanigen provided an "update" concerning its LIVE-AIR trial stating, in pertinent part, that an additional "interim analysis for safety" had been conducted by the study's DSMB. Based on this data and "feedback from FDA regulators regarding the amount of patient data that would be required to support [a BLA]," Humanigen "decided not to conduct an interim analysis for efficacy."

**Topline Data from LIVE-AIR**

56. On March 29, 2021, Humanigen announced positive topline results from the LIVE-AIR trial. In pertinent part, Humanigen stated that the "[t]rial results showed that patients who received lenzilumab and other treatments, including steroids and/or remdesivir, had a 54% greater relative likelihood of survival without the need for IMV [invasive mechanical ventilation] compared with patients receiving placebo and other treatments. These results are statistically significant."

57. At the same time, the topline results also revealed that the trial's secondary endpoint of overall survival (as opposed to ventilator-free survival) was not "statistically significant."

58. In the announcement, Humanigen quoted Durrant who stated that, "Our next step is to submit an application for Emergency Use Authorization (EUA) to the Food and Drug Administration (FDA) as soon as possible."

**Humanigen's EUA Application**

59. On May 28, 2021, Humanigen announced that it had submitted the

lenzilumab EUA to the FDA. The announcement stated, in pertinent part, that "[t]his EUA application follows positive results from the LIVE-AIR Phase 3 clinical trial evaluating the ability of lenzilumab to improve the likelihood of survival without ventilation (SWOV) in newly hospitalized COVID-19 patients."

**Advancement of ACTIV/BET-B**

60. On July 30, 2021, Humanigen announced that the NIH had advanced the ACTIV-5/BET-B study to a Phase 2/3 study; modified the primary endpoint to SWOV, the same endpoint used in the LIVE-AIR study; and amended the study to include 400 patients overall. The announcement also quoted Durrant who stated, in relevant part, that: "We believe ACTIV-5/BET-B, along with LIVE-AIR, will provide the sufficient size and statistical power typically required for a BLA [Biologics License Application] to be submitted to FDA."

61. In response to this news, Cantor Fitzgerald issued an analyst report dated July 30, 2021, stating that: "We think this is good news for the company and underscores our belief that EUA [Emergency Use Authorization] will be granted for lenzilumab to treat COVID-19 this summer. We expect ~$1B of sales for lenzilumab 12 months post launch."

62. Similarly, on August 2, 2021, Oppenheimer wrote in a report that: "Encourage investors to remain focused on FDA EUA process in the US. Expect EUA approval based on evidence of potential additive survival benefit from lenzilumab

beyond current SOC [standard of care] of steroids and directive antiviral therapy."

63. At the same time though, other analysts noted that the FDA had not yet granted the EUA and updated their analyses to account for the delay. For example, on August 10, 2021, Roth Capital Partners also wrote that: "We have modified our estimates for Q221 and FY2021 for Humanigen. . . . The EUA is yet to be approved. Humanigen management stated it continues to have discussions with regulatory authorities. We are removing lenzilumab revenue for Q221 and reducing FY2021 assumptions . . . ."

**The FDA Delays Approval for Humanigen's EUA**

64. On August 12, 2021, Humanigen announced its second quarter 2021 financial results, stating, *inter alia*, that since submitting the lenzilumab EUA to the FDA, "the company has responded to several requests from the [FDA] regarding the application" and that "the company anticipates that ACTIV5/BET-B may serve as a second confirmatory study required for submission to FDA as part of a [BLA] that the company would submit if the ACTIV-5/BET-B data further validate the benefits of lenzilumab in COVID-19 patients."

65. Analysts took note of the FDA's delayed response. On August 12, 2021, Oppenheimer wrote: "[Humanigen] provided regulatory updates on lenzilumab and published 2Q21 financial results . . . . [W]e view 2-3 months for EUA decision by FDA as reasonable . . . ." Meanwhile, also on August 12, 2021, Jefferies stated: "We

caught up with mgmt. after the earnings release. Mgmt remains confident about the EUA approval and believe the decision could be any day, and most likely in August. HGEN responded to several requests from the FDA and doesn't expect more FDA requests. We think Lenz is well positioned for winning EUA approval. . . . The stock could move up +60-80% if approved. Downside is limited to -20-30% ***if larger safety dataset or add'l trial requested***" (emphasis added).

**The FDA Rejects Humanigen's EUA**

66. On September 8, 2021, Humanigen issued a press release announcing that the FDA had rejected the lenzilumab EUA, stating in relevant part that:

> [T]he U.S. FDA has declined its request for emergency use authorization of lenzilumab to treat newly hospitalized COVID-19 patients. In its letter, FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19.

67. On this news, Humanigen's stock price fell $7.14 per share, or 47.25%, to close at $7.97 per share on September 9, 2021. Despite this decline in Humanigen's stock price, Humanigen securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding lenzilumab's clinical and commercial prospects.

**Another Type B Meeting with the FDA**

68. On November 12, 2021, Humanigen told investors that it had

participated in a second Type B meeting with the FDA following the FDA's rejection of the lenzilumab EUA.

69. In pertinent part, Humanigen stated that it had "requested and . . . been granted a Type B meeting with FDA"; that "[i]ncluded in the briefing materials for the meeting request were day 60 data as well as detailed CRP analysis from the LIVE-AIR study"; that "[w]e intend to submit a [BLA] to FDA for lenzilumab in the treatment of hospitalized COVID-19 patients"; and that "we plan to include the results of the expanded ACTIV-5/BET-B study as a basis for a BLA-confirmatory study for lenzilumab and believe data from ACTIV-5/BET-B, along with LIVE-AIR, should provide the sufficient size and statistical power typically required for a BLA to be submitted to FDA."

**Kiniksa Pharmaceuticals Announces Negative Results**

70. On December 28, 2021, Kiniksa Pharmaceuticals, Ltd. announced results from its Phase 3 trial of mavrilimumab in COVID-19-related acute respiratory syndrome. Similar to lenzilumab, mavrilimumab was an investigational fully human monoclonal antibody that targeted granulocyte macrophage colony stimulating factor receptor alpha, or GM-CSFRα. According to Kiniksa Pharmaceuticals' press release, "the Phase 3 portion of the Phase 2/3 trial of mavrilimumab in COVID-19-related acute respiratory syndrome (ARDS) did not meet the primary efficacy endpoint."

71. Mavrilimumab, like lenzilumab, was initially developed for use with CAR-T therapies. In fact, in December 2019, Kiniksa Pharmaceuticals entered into a

clinical collaboration with Kite Pharmaceuticals to initiate a Phase 2 clinical trial evaluating the combination of Yescarta and mavrilimumab in relapsed or refractory large B-Cell lymphoma, similar to Humanigen and its agreement with Kite Pharmaceuticals. The objective of the Phase 2 trial was to determine the effect of mavrilimumab on the safety of Yescarta, which was the precise objective Humanigen had in its pre-COVID testing for lenzilumab.

72. Kiniksa Pharmaceuticals' mavrilimumab worked similarly to Humanigen's lenzilumab. The drug inhibited GM-CSF which, in turn, would disrupt CAR-T therapy side-effects without preventing the CAR-T therapy itself from working.

73. Once COVID emerged, Kiniksa Pharmaceuticals began evaluating mavrilimumab's use in COVID-related acute respiratory distress syndrome. As early as April 2020, Kiniksa Pharmaceuticals announced clinical data from an open-label treatment protocol testing mavrilimumab in COVID patients and, as of July 30, 2020, was enrolling patients for its Phase 2 portion of a Phase 2/3 clinical trial to further test mavrilimumab in COVID patients. In April 2021, Kiniksa Pharmaceuticals announced that the Phase 2 portion of its clinical trial achieved its primary efficacy endpoint. However, in December 2021, Kiniksa Pharmaceuticals announced that the Phase 3 portion of its clinical trial did not meet its primary efficacy endpoint, which was the proportion of patients alive and free of mechanical ventilation at Day 29.

**Lenzilumab Fails to Meet Primary Endpoint**

74. On January 5, 2022, Humanigen issued a press release announcing that target enrollment in the Phase 2/3 ACTIV-5/BET-B study had been achieved. The press release quoted Durrant, who stated, in relevant part:

> Completion of target enrollment in ACTIV-5/BET-B is a significant milestone in the development of lenzilumab . . . . We have alignment with the FDA that, if the trial is successful, we can include the results from ACTIV-5/BET-B in an amended [EUA] submission for lenzilumab for hospitalized patients with COVID-19. We look forward to sharing the topline results from ACTIV-5, when available, and submitting an amended EUA.

75. On May 5, 2022, Humanigen filed a quarterly report for the first quarter of 2022, stating in pertinent part that, "[t]he next anticipated step in Humanigen's development program for lenzilumab in COVID-19 is the release of results from the . . . ACTIV-5/BET-B trial" and that, "[i]f confirmatory of the findings of the CRP subgroup from Humanigen's LIVE-AIR study, its plans to include the results from ACTIV-5/BET-B in an amendment to its [EUA] submission to the [FDA.]"

76. On July 12, 2022, after market hours, Humanigen disclosed that lenzilumab had failed to show statistical significance on the primary endpoint of the ACTIV-5/BET-B study, stating, in relevant part:

> Humanigen . . . has been informed of preliminary topline results from the National Institute of Allergy and Infectious Diseases' (NIAID) ACTIV-5/BET-B trial evaluating lenzilumab plus remdesivir versus placebo plus remdesivir in hospitalized COVID-19 patients. The trial did not achieve statistical significance on the primary endpoint. . . . The data also showed a non-significant trend toward a reduction in mortality

in the overall patient population[.]

77. Humanigen further provided investors with a quote from Durrant, stating in pertinent part as follows: "We are grateful for the constructive collaboration with NIH/NIAID, while the ACTIV-5/BET-B study showed signs of a clinical effect, the benefit demonstrated was not able to confirm the positive results we saw in our Phase 3 LIVE-AIR study. . . . ***In order to prove the therapeutic benefits of immunomodulators, platform studies comprising thousands of patients have been necessary***. With the continued resurgence of COVID-19, further exploration of variant agnostic treatments to improve outcomes in hospitalized COVID-19 patients should be a priority" (emphasis added).

78. On this news, Humanigen's stock price fell $2.38 per share, or 79.6%, to close at $0.61 per share on July 13, 2022.

79. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Humanigen's securities, Plaintiffs and other Class members have suffered significant losses and damages.

## MATERIALLY FALSE AND MISLEADING STATEMENTS

### May 15, 2020

80. On May 15, 2020, after market hours, Humanigen filed its quarterly report on Form 10-Q for the period ended March 31, 2020. Durrant signed the report. In pertinent part, Humanigen stated as follows in the quarterly report:

> The recent coronavirus pandemic, which is due to the SARS-CoV-2 virus and leads to the condition referred to as COVID-19, is frequently characterized in the later and sometimes fatal stages by severe, progressive viral pneumonia that can progress to acute respiratory distress syndrome ("ARDS"), respiratory failure and death. Recent publications indicate that ARDS in this setting is caused by the body's autoimmune response to CRS. Published data point to GM-CSF being a key triggering cytokine, with elevated levels especially in those patients who transition to the Intensive Care Unit ("ICU").
>
> In response to this published data indicating that GM-CSF inhibition may play a role in treating patients with COVID-19, ***the Company is developing lenzilumab in COVID-19 in a Phase III potential registration study***. The Company has commenced enrollment in a multicenter randomized, placebo-controlled, double-blind clinical trial with lenzilumab for the prevention of respiratory failure and/or death in hospitalized patients with severe pneumonia associated with SARS-CoV-2 infection (Clinicaltrials.gov # NCT04351152).
>
> . . .
>
> ***Recent data from China and the subject of a pre-publication titled "Aberrant pathogenic GM-CSF+ T cells and inflammatory CD14+CD16+ monocytes in severe pulmonary syndrome patients of a new coronavirus", supports the hypothesis that cytokine storm-induced immune mechanisms have contributed to patient mortality with the current pandemic strain of coronavirus***.

(emphasis added)

81. The statements identified above were false and/or materially misleading. Lenzilumab inhibited GM-CSF cytokines which were integral to normal lung functions, as academic literature and medical studies confirmed. Thus, lenzilumab presented material patient-safety risks if used to treat lung dysfunction in COVID patients. Humanigen did not disclose this risk and, as such, Humanigen's discussion

of its "Phase III potential registration study" was materially misleading because it concealed significant known risks from investors. By not disclosing this material information about lenzilumab's negative effect on normal lung function, Humanigen precluded investors from properly evaluating the risks associated with the company's "potential registration study."

82. Furthermore, the statements identified above were false and/or materially misleading because they did not disclose that a substantial amount of published academic and medical literature had already concluded that GM-CSF played a vital role in healthy and normal lung function. In the above statement, Humanigen referenced "[r]ecent data from China" and a "pre-publication" paper as being supportive of using lenzilumab to treat COVID patients but, at the same time, did not disclose that the majority of research and literature contradicted that conclusion. Thus, by describing "[r]ecent data from China" and the "pre-publication" paper without providing investors a description of the research and literature as a whole, Humanigen misled investors to believe that lenzilumab could be used as a COVID treatment without unreasonable risk.

**August 5, 2020**

83. On August 5, 2020, after market hours, Humanigen filed a prospectus relating to the registration and/or resale of 82,563,584 shares of its common stock to be listed on the NASDAQ. At the time, the last reported sale price of Humanigen's

common stock on the OTCQB was $4.95/share. Durrant signed the registration statement underlying the prospectus. In pertinent part, Humanigen's prospectus stated as follows:

> ***We believe that, as an upstream regulator of cytokine storm, GM-CSF neutralization with lenzilumab may offer advantages over other immunomodulator strategies*** that either target other downstream cytokines such as IL-1, IL-6, CCR5 or MIP-1 alpha or are broadly immunosuppressive and target cytokine signaling pathways non-selectively through JAK inhibition. In addition, ***lenzilumab is the only immunomodulator that was in an active clinical trial in another indication to prevent cytokine storm prior to embarking upon the Phase III COVID-19 trial and is currently the only agent in an active Phase III trial targeting GM-CSF***.
>
> . . .
>
> ***As an upstream regulator of cytokine storm, GM-CSF neutralization with lenzilumab may offer advantages over other immunomodulator strategies*** that either target other downstream cytokines such as IL-1, IL-6, CCR5 or MIP-1 alpha or are broadly immunosuppressive and target cytokine signaling pathways non-selectively through JAK inhibition. In addition, ***lenzilumab is the only immunomodulator that was in an active clinical trial to prevent cytokine storm prior to COVID-19 and is currently the only agent in an active Phase III trial targeting GM-CSF***.

(emphasis added)

84. The statements identified above were false and/or materially misleading. Lenzilumab inhibited GM-CSF cytokines which were integral to normal lung functions, as academic literature and medical studies confirmed. Thus, lenzilumab presented material patient-safety risks if used to treat lung dysfunction in COVID patients. Humanigen did not disclose this adverse material information which

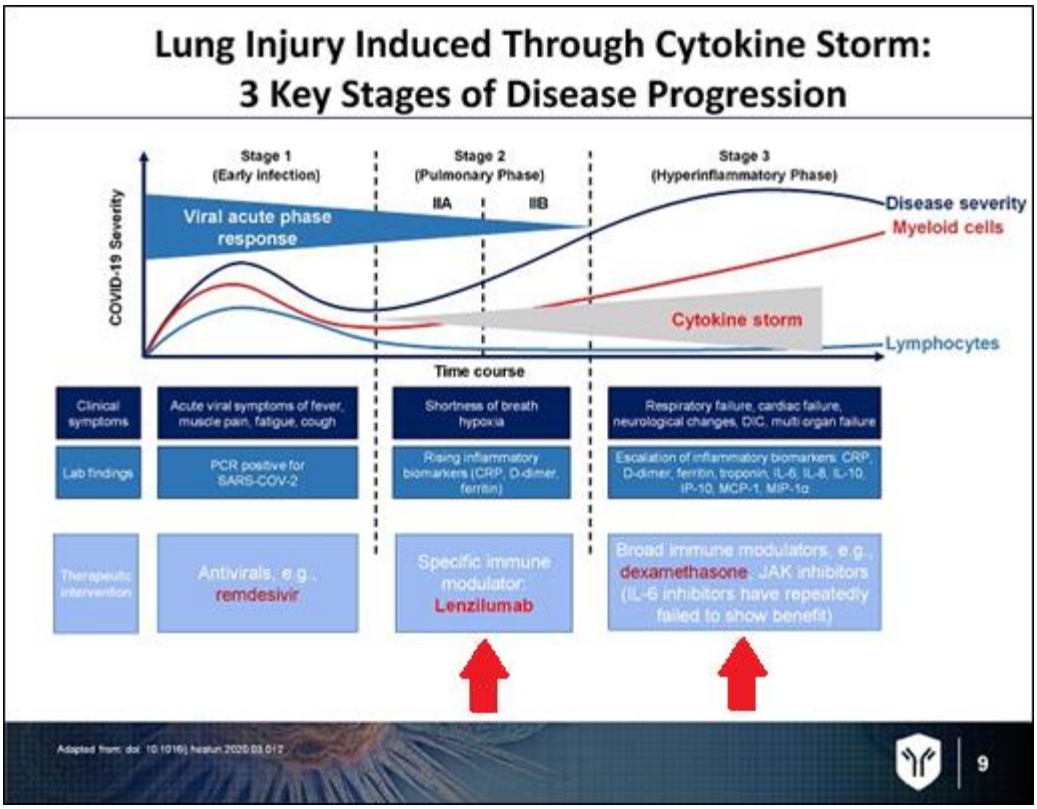
contradicted its statement that "lenzilumab may offer advantages over other immunomodulator strategies." These statements materially misled investors and, as a result, did not provide them with an accurate or truthful description of lenzilumab's clinical benefit for treating COVID patients.

85. Furthermore, the statements identified above were false and/or materially misleading because it misrepresented the status of past and current clinical trials. Kiniksa Pharmaceuticals' GM-CSF drug, mavrilimumab, had previously been studied in a clinical trial to evaluate its ability to reduce side-effects from CAR-T therapy. Further, once COVID began, Kiniksa Pharmaceuticals commenced a Phase 2/3 clinical trial and was already enrolling patients as of July 30, 2020. Consequently, Humanigen's claims that lenzilumab was the "only immunomodulator that was in an active clinical trial in another indication" and that it was the "only agent in an active Phase III trial targeting GM-CSF" were materially misleading and, as a result, provided investors with false information about Humanigen's competition for developing a COVID treatment.

**August 10, 2020**

86. On August 10, 2020, Humanigen participated in the BTIG Virtual Biotechnology Conference. Durrant and Chappell presented on behalf of Humanigen. Humanigen presented a slide presentation during the conference.

87. In pertinent part, the presentation contained the following slide:




88. The above slide and accompanying presentation were false and/or materially misleading. Humanigen discussed lenzilumab's application and use in COVID patients and, as identified by the red arrows in the above slide, compared it to other inhibitors. While Humanigen told investors that "JAK inhibitors" such as IL-6 (Interleukin 6) have "repeatedly failed to show benefit," it did not disclose the adverse effects of using lenzilumab, a GM-CSF inhibitor, in COVID patients. Thus, by failing to disclose the adverse effects it had on lung function, Humanigen misled investors to believe that lenzilumab did not have negative clinical benefits along the lines of the other inhibitors featured in the slide.

**August 14, 2020**

89. On August 14, 2020, after market hours, Humanigen published its

quarterly report on Form 10-Q for the second quarter of 2020. Durrant signed the quarterly report on behalf of Humanigen.

90. In pertinent part, the quarterly report stated as follows:

> The coronavirus pandemic, which is due to the SARS-CoV-2 virus and leads to the condition referred to as COVID-19, is frequently characterized in the later and sometimes fatal stages by severe and critical, progressive viral pneumonia that can progress to acute respiratory distress syndrome ("ARDS"), respiratory failure and death. Publications have indicated that ARDS in this setting is caused by the body's autoimmune response to CRS. Published data point to GM-CSF being a key triggering cytokine, with elevated levels especially in those patients who transition to the Intensive Care Unit ("ICU").
>
> ***In response to this published data indicating that GM-CSF inhibition may play a role in treating patients with COVID-19, the Company is developing lenzilumab in patients with COVID-19 in a Phase III study***. Given the severity of the pandemic and the lack of approved therapies for COVID-19, ***the Company believes that this single Phase III study may be suitable for registration and depending on the results of this study may file for approval with the FDA***. The Company has commenced enrollment in a multicenter randomized, placebo-controlled, double-blind clinical trial to assess whether lenzilumab can reduce the time to recovery in hospitalized subjects with severe or critical COVID-19 pneumonia. The first patient was dosed with lenzilumab on May 5, 2020.

(emphasis added)

91. The statements identified above were false and/or materially misleading. Lenzilumab inhibited GM-CSF cytokines which were integral to normal lung functions, as academic literature and medical studies confirmed. Thus, lenzilumab presented material patient-safety risks if used to treat lung dysfunction in COVID patients. Humanigen did not disclose this risk and, as such, Humanigen's statement

that its "single Phase III study" could be "suitable for registration" was materially misleading because it concealed significant known risks from investors. By not disclosing this material information about lenzilumab's negative effect on normal lung function, Humanigen precluded investors from properly evaluating the risks associated with the company's "Phase III study."

92. Furthermore, the statements identified above were false and/or materially misleading because they did not disclose that a substantial amount of published academic and medical literature had already concluded that GM-CSF played a vital role in healthy and normal lung function. In the above statement, Humanigen referenced "published data" as being supportive of using lenzilumab to treat COVID patients but, at the same time, did not disclose that the majority of research and literature contradicted that conclusion. Thus, by describing "published data" without any qualification or description of the research and literature as a whole, Humanigen misled investors to believe that lenzilumab could be used as a COVID treatment without unreasonable risk.

**September 18, 2020**

93. On September 18, 2020, after market hours, Humanigen filed a prospectus with the SEC announcing a public offering of 8 million shares. Durrant signed the registration statement underlying the prospectus.

94. Humanigen's prospectus discussed lenzilumab's application and the

company's current clinical trials. In pertinent part, the prospectus stated as follows:

> We believe that, as an upstream regulator of cytokine storm, ***GM-CSF neutralization with lenzilumab may offer advantages over other immunomodulator strategies*** that either target other downstream cytokines such as IL-1, IL-6, CCR5, MCP-1, IP-10, TNF-α, or MIP-1α (the ligand for the CCR5 receptor) or are broadly immune-suppressive and target cytokine signaling pathways non-selectively through JAK inhibition or steroids which have well documented lympholytic properties. In addition, we believe, ***lenzilumab is the only immunomodulator that was in an active clinical trial in a non-COVID indication to prevent cytokine storm prior to embarking upon the Phase III COVID-19 trial***. According to clintrials, ***lenzilumab is currently the only agent in an active Phase III trial targeting GM-CSF***. In addition, lenzilumab may have additional benefits on T-cell function as demonstrated in preclinical models with CAR-T.
>
> . . .
>
> We are currently enrolling patients in a Phase III multi-center, randomized, placebo-controlled, double-blinded, clinical trial in the setting of COVID-19. ***The Phase III trial will assess the safety and efficacy of lenzilumab in improving time to recovery and reducing severe outcomes in hospitalized adult patients with confirmed severe or critical COVID-19 pneumonia and may serve as the basis for EUA and/or submission of a Biologics License Application ("BLA") for approval of lenzilumab for COVID-19 pneumonia***. The first patient was dosed in May 2020. There are currently 17 clinical sites across the US and we are targeting 12 clinical sites in Brazil.

(emphasis added)

95. The above statements were false and/or materially misleading. Humanigen discussed lenzilumab's application and use in COVID patients compared it to other inhibitors. While Humanigen referred specifically to "other immunomodulator strategies" as ineffective or having demonstrated negative results, it did not disclose the adverse effects of using lenzilumab, a GM-CSF inhibitor, in

COVID patients. Thus, by failing to disclose the adverse effects it had on lung function, Humanigen misled investors to believe that lenzilumab did not have negative clinical benefits along the lines of the other inhibitors referenced.

96. In addition, Humanigen's statement that its "Phase III trial" could "serve as the basis for EUA and/or [BLA]" was materially misleading because it concealed significant known risks from investors. By not disclosing material information about lenzilumab's negative effect on normal lung function, Humanigen precluded investors from properly evaluating the risks associated with the company's "Phase III trial."

97. The statements identified above were also false and/or materially misleading because it misrepresented the status of past and current clinical trials. Given that Kiniksa Pharmaceuticals' GM-CSF drug, mavrilimumab, had previously been studied in a clinical trial to evaluate its ability to reduce side-effects from CAR-T therapy and was also then-currently the subject of a Phase 2/3 clinical trial for use in COVID patients, Humanigen misrepresented that lenzilumab was the "only immunomodulator that was in an active clinical trial in a non-COVID indication" and "currently the only agent in an active Phase III trial targeting GM-CSF" and, as a result, provided investors with false information about Humanigen's competition for developing a COVID treatment.

**November 6, 2020**

98. On November 6, 2020, before market hours, Humanigen published a press release announcing "positive interim Phase 3 data" from the LIVE-AIR trial.

99. The press release included a quote from Chappell stating that, "we believe the Phase 3 trial is ***significantly de-risked***" and that Humanigen would be adding patients to the trial which "***further supports our plans*** for Emergency Use Authorization (EUA) and Biologics License Application (BLA) submission" (emphasis added).

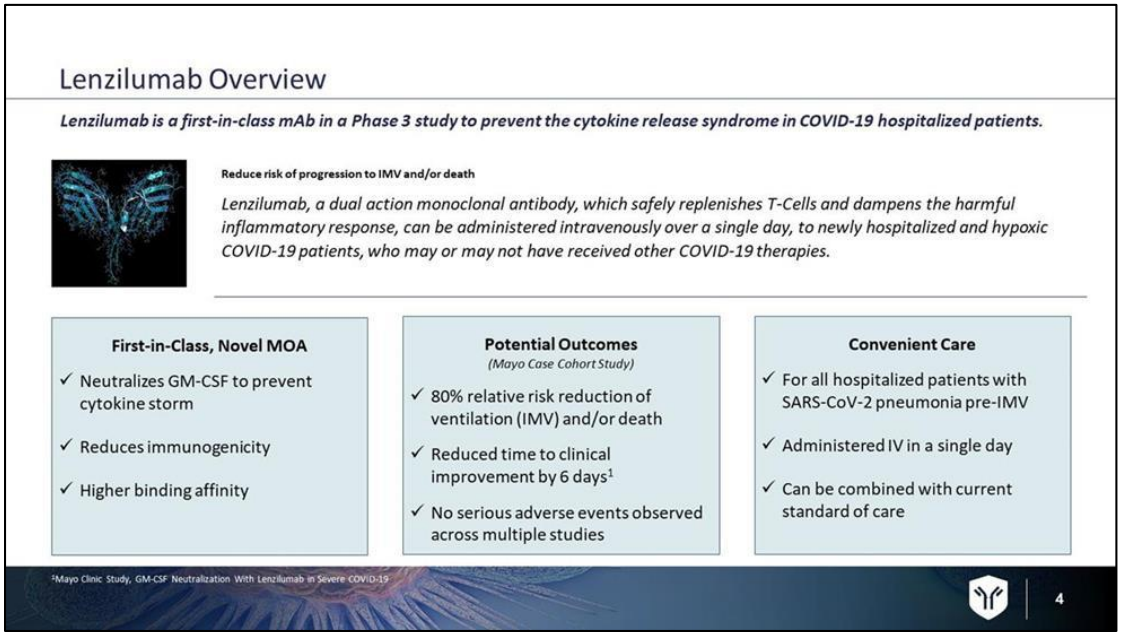
100. The statements identified above were false and/or materially misleading. Chappell's representation that the LIVE-AIR trial was "significantly de-risked" and continued to "support [Humanigen's] plans" for approval was materially misleading because it concealed significant known risks from investors. By not disclosing material information about lenzilumab's negative effect on normal lung function, Humanigen precluded investors from properly evaluating the risks associated with the company's trial and prospects for FDA-approval.

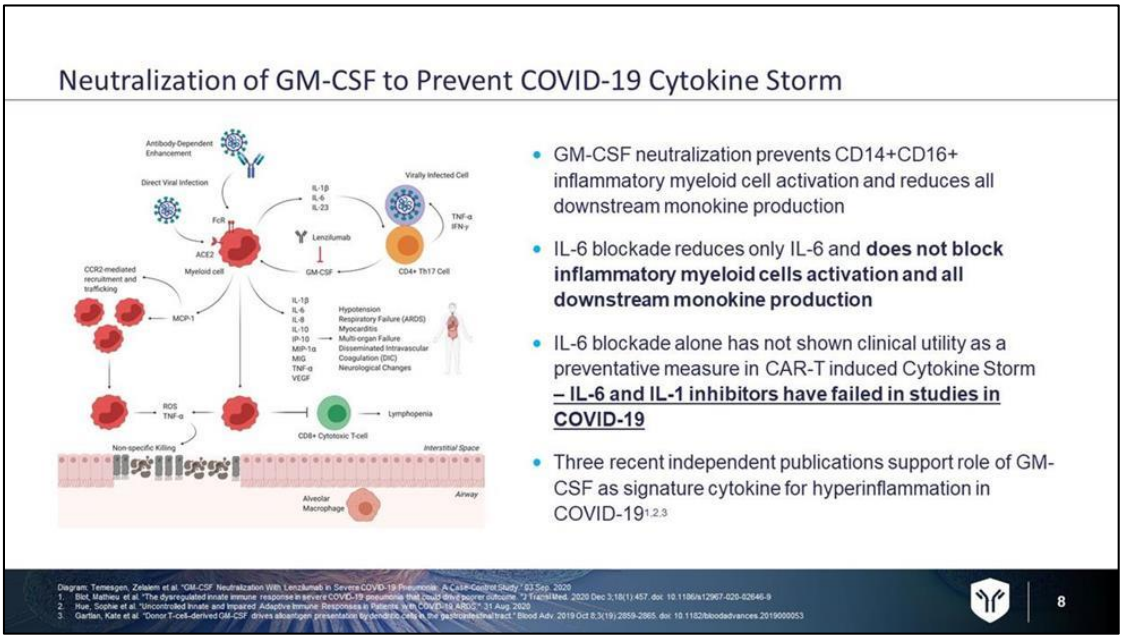
**January 13, 2021**

101. On January 13, 2021, before market hours, Humanigen participated in the JPMorgan Healthcare Conference. Durrant and Chappell presented on behalf of Humanigen.

102. During the conference, Durrant and Chappell presented the following

slides:




103. When discussing the above slides, Durrant stated in pertinent part as follows:

> So on to Slide 4, lenz overview. Lenz is our anti-human GM-CSF monoclonal antibody. This is a very different monoclonal antibody and a very different mechanism of action from the neutralizing monoclonal

> antibodies that -- being used in the outpatient setting for COVID as a prevention for hospitalization. Those neutralizing antibodies target the virus, fight protein, and they try and prevent the virus from entering and infecting cells.
>
> . . .
>
> So some important unique aspects of lenz, you can see in the middle of this slide here. Lenz has a dual mechanism of action in helping replenish T cells and dampening the hyperinflammation. The full course of lenz can be administered to hospitalized hypoxic patients in a single day. And lenz doesn't have any renal or hepatic impairment limitations. So it can be used in combination with other therapies, and we've seen no serious adverse events in hundreds of patients in multiple different clinical settings. ***So there's been an excellent safety and tolerability profile to date***.

(emphasis added)

104. The slides and statements identified above were false and/or materially misleading. Humanigen discussed lenzilumab's application and use in COVID patients compared it to other inhibitors. While Humanigen referred specifically to other immunomodulator strategies, including IL-6 and IL-1, as "hav[ing] failed in studies in COVID-19," it did not disclose the adverse effects of using lenzilumab, a GM-CSF inhibitor, in COVID patients. At the same time, Durrant referred to lenzilumab as having an "excellent safety and tolerability profile to date" when, in reality, academic and medical literature materially contradicted this conclusion.

**March 10, 2021**

105. On March 10, 2021, after market hours, Humanigen filed with the SEC its annual report on Form 10-K for fiscal 2020. Durrant and Chappell signed the

annual report.

106. In the annual report, Humanigen described the "scientific rationale" for using lenzilumab to treat COVID patients. The annual report stated, in pertinent part, as follows:

> Lenzilumab neutralizes GM-CSF. The coronavirus pandemic, which has been triggered by the SARS-CoV-2 virus and leads to the condition referred to as COVID-19, is characterized in the later and sometimes fatal stages by lung dysfunction and, in many patients, multi-organ impairment, which is triggered by Cytokine Release Syndrome ("CRS"), or cytokine storm. Publications have pointed to GM-CSF as being a signature cytokine in this process, with elevated GM-CSF levels correlated to poorer outcomes and sometimes ventilator use and Intensive Care Unit ("ICU") admission.
>
> COVID-19 has three distinct phases: early infection, pulmonary/inflammatory and hyperinflammatory. As shown on the diagram below, lenzilumab is being studied for use in patients that are in the pulmonary/inflammatory phase who are hospitalized and hypoxic.
>
> . . .
>
> The severe clinical features associated with some COVID-19 infections result from an inflammation-induced lung injury which may require supplemental oxygen through a nasal cannula, non-invasive or invasive mechanical ventilation or Extra Corporeal Mechanical Oxygenation (ECMO) and sometimes ICU care. This lung injury is a result of a hyperinflammatory dysregulation of the immune system and associated with cytokine storm. The lung injury that leads to death is not directly related to the virus but appears to be a result of a hyper-reactive immune response to the virus triggering a cytokine storm that can continue even after viral titers remain stable or even begin to fall.
>
> . . .
>
> Data from National Scientific Review (2020, Vol. 7, No. 6) titled "Pathogenic T-cells and inflammatory monocytes incite inflammatory

storms in severe COVID-19 patients", supports the hypothesis that GM-CSF induced cytokine storm immune mechanisms have contributed to patient mortality with the current pandemic strain and, we believe, in multiple variants, of coronavirus, and there is increasing acceptance that this pathophysiology may be responsible for worsening of clinical status and poor outcomes. The authors noted that steroid treatment in such cases has been disappointing in terms of outcome but suggested that a monoclonal antibody that targets GM-CSF may prevent or curb the hyper-active immune response caused by COVID-19 in this setting. Three recent publications point to GM-CSF as a so-called 'signature cytokine' including the largest inflammatory marker study in over 600 patients from a multicenter study in the UK.

. . .

While early studies demonstrated elevated GM-CSF levels in both ICU and non-ICU treated COVID-19 patients, one of these three more recent studies showed a positive association with disease severity and outcome, in agreement with reports of elevated frequencies of GM-CSF+ Th1 cells in patients with COVID-19 requiring ICU treatment. . . . .

A second independent study reported serum concentrations of GM-CSF were significantly higher in COVID-19 patients. In this study, increased serum concentrations of IL-8, IL-10 and GM-CSF were associated with disease severity. . . . .

A third independent study reported a significant correlation between the duration of mechanical ventilation ("MV") and GM-CSF ($p < 0.0001$), IL-10 ($p < 0.0001$), IP-10 ($p < 0.0001$), MCP-1 ($p = 0.001$), CX3CL1 ($p = 0.0233$), and Granzyme B ($p = 0.0143$). . . . .

Similar to patients receiving CAR-T therapy, the development of CRS in patients with COVID-19 has been associated with elevation of CRP, ferritin, MCP-1, MIP-1 alpha, INF-gamma, TNF-alpha, and IL-6, as well as correlating with respiratory failure, ARDS, and adverse clinical outcomes. . . . We believe that these new data suggest that GM-CSF may be a critical triggering cytokine in the increased mortality in COVID-19.

107. The statements identified above were false and/or materially misleading.

While Humanigen provided investors with the "scientific rationale" for using lenzilumab to treat COVID patients, it identified only positive support for the treatment while concealing the substantial amount of published academic and medical literature that had already concluded that GM-CSF played a vital role in healthy and normal lung function. This academic and medical literature materially contradicted Humanigen's "scientific rationale" for using lenzilumab to treat COVID patients and concealed the significant patient risks that lenzilumab posed to COVID patients. Thus, by describing only supportive literature without providing a description of the research and literature as a whole, Humanigen misled investors to believe that lenzilumab could be used as a COVID treatment without unreasonable risk and, in turn, provided investors with a materially misleading description of the regulatory risks Humanigen faced with respect to obtaining an EUA and/or BLA approval from the FDA.

108. Humanigen's annual report also stated, in pertinent part, that:

> ***The scientific rationale behind the hypothesis that GM-CSF is a cause of the cytokine storm that leads to adverse results in COVID-19 patients is still being tested and may not prove accurate.***
>
> The hypothesis that elevated GM-CSF levels may contribute to cytokine storm-induced immune mechanisms that places patients at greater risk of ICU admission and mortality with the current pandemic strain of coronavirus is unproven. Certain data are the subject of pre-publication papers that have not been peer-reviewed and may not be substantiated. If this hypothesis is not ultimately proven through clinical trials which are underway, the potential for lenzilumab to play a meaningful role in a COVID-19 therapy likely would decrease or be eliminated. We cannot

assure you that our exploratory efforts in this respect will be fruitful.

(emphasis in original)

109. The above statements were false and/or materially misleading. A substantial amount of academic and medical literature already concluded that GM-CSF was vital for healthy lung function and, therefore, squarely contradicted the "hypothesis" that lenzilumab could be used as a COVID treatment. Notwithstanding, Humanigen told investors that "[c]ertain data" from "pre-publication papers" supported the "hypothesis" without disclosing anything about the negative data. The above statement falsely represented that negative data did not exist and/or the only data that did exist was positive and supportive with respect to lenzilumab's use for COVID treatment, which was not true. This prevented investors from understanding the true risks that existed concerning whether Humanigen's "hypothesis" would be "ultimately proven" and, in turn, the likelihood that lenzilumab would receive FDA-approval for treatment in COVID patients.

**May 13, 2021**

110. On May 13, 2021, after market hours, Humanigen filed its quarterly report with the SEC on Form 10-Q. Durrant signed the quarterly report on behalf of Humanigen.

111. The quarterly report provided investors with an update concerning its regulatory approval efforts for lenzilumab. In pertinent part, the quarterly report stated as follows:

> We have shared the top-line data on just the primary endpoint and one secondary endpoint (the only data then available while the remaining analysis was pending) with the FDA in a Pre-EUA Type B meeting in mid-April 2021. We are preparing to submit an EUA application at the end of May 2021. As requested by the FDA, the EUA application will include secondary endpoints and supplemental data analysis from LIVE-AIR, including those referenced in the MedRxiv publication, as well as additional stability and compatibility information required for the CMC section of the EUA application. ***There can be no assurance that the data published on MedRxiv will be sufficient for an EUA or that the FDA will not require additional information in order to grant an EUA***. If the EUA is granted, we could begin to commercialize lenzilumab for the treatment of newly hospitalized COVID-19 pneumonia patients.

(emphasis added)

112. The statements identified above were false and/or materially misleading. According to Humanigen, top-line data from the LIVE-AIR trial met its primary endpoint but failed to meet its secondary endpoint for overall survival as not "statistically significant," thereby showing limited evidence of efficacy in this small trial. In addition, given the historical literature concerning GM-CSF and its vital role in healthy lung function as well as the FDA's guidance relating to regulatory approval for COVID treatments, an increased amount of patient safety data was necessary for demonstrating lenzilumab's clinical benefit as a COVID treatment. The LIVE-AIR trial did not provide Humanigen with enough safety data to support an EUA application. Instead of disclosing this to investors, Humanigen simply stated that it could not give "assurance" that its data would be "sufficient" for the EUA, which provided investors with a materially false representation of the risks Humanigen faced

with respect to the EUA application.

**July 30, 2021**

113. On July 30, 2021, Humanigen issued a press release announcing that the NIH had advanced the ACTIV-5/BET-B study to a Phase 2/3 study. The press release quoted Durrant who stated, in relevant part, that: "We believe ACTIV- 5/BET-B, along with LIVE-AIR, will provide the sufficient size and statistical power typically required for a BLA to be submitted to FDA."

114. The statements identified above were false and/or materially misleading. According to Humanigen, top-line data from the LIVE-AIR trial met its primary endpoint but failed to meet its secondary endpoint for overall survival as not "statistically significant," thereby showing limited evidence of efficacy. In addition, given the historical literature concerning GM-CSF and its vital role in healthy lung function as well as the FDA's guidance relating to regulatory approval for COVID treatments, an increased amount of patient safety data was necessary for demonstrating lenzilumab's clinical benefit as a COVID treatment. The LIVE-AIR trial did not provide Humanigen with enough safety data to support an EUA application. Durrant did not disclose this in the press release. Instead, he stated that the ACTIV-5/BET-B data "along with LIVE-AIR" would provide the data necessary that is "typically required for a BLA," which left investors with the false impression that Humanigen had sufficiently supported its EUA application with enough data

when, in fact, it had not.

**August 12, 2021**

115. On August 12, 2021, Humanigen issued a press release announcing its second quarter 2021 financial results, stating, *inter alia*, that since submitting the lenzilumab EUA to the FDA, "the company has responded to several requests from the [FDA] regarding the application" and that "the company anticipates that ACTIV-5/BET-B may serve as a second confirmatory study required for submission to FDA as part of a [BLA] that the company would submit if the ACTIV-5/BET-B data further validate the benefits of lenzilumab in COVID-19 patients."

116. The statements identified above were false and/or materially misleading because it failed to disclose that the LIVE-AIR trial did not provide enough safety data to support an EUA application. By discussing its plans to use the ACTIV-5/BET-B data for the BLA application, Humanigen provided investors with a false representation and understanding of the sufficiency of its EUA application that had already been submitted.

117. On August 12, 2021, in addition to the press release, Humanigen filed a quarterly report on Form 10-Q with the SEC reporting its financial and operational results for the second quarter of 2021. Durrant signed the quarterly report on behalf of Humanigen.

118. In pertinent part, the quarterly report stated as follows:

> The Company submitted an application for Emergency Use Authorization ("EUA") of lenzilumab to the U.S. Food and Drug Administration ("FDA") at the end of May 2021. As requested by FDA, the EUA application included secondary endpoints and supplemental data analysis from LIVE-AIR as well as additional stability and compatibility information required for the Chemistry Manufacturing and Control ("CMC") section of the EUA application. Since our initial submission of the application for EUA, we have responded to several requests from FDA regarding the application. ***There can be no assurance that the data the Company has submitted to FDA will be sufficient for an EUA***, or that FDA will not require additional information in order to grant an EUA.

(emphasis added)

119. The statements identified above were false and/or materially misleading. The LIVE-AIR trial did not provide Humanigen with enough safety data to support an EUA application. Instead of disclosing this to investors, Humanigen simply stated that they could not give "assurance" that its data would be "sufficient" for the EUA, which provided investors with a materially false representation of the risks Humanigen faced with respect to the EUA application.

120. The quarterly report also stated, in pertinent part, as follows:

> ***The scientific rationale behind the hypothesis that GM-CSF is a cause, or the main cause, of the cytokine storm that leads to adverse results in COVID-19 patients is still being tested and may not prove accurate.***
>
> The hypothesis that elevated GM-CSF levels may contribute to cytokine storm-induced immune mechanisms that places patients at greater risk of ICU admission and mortality with the current pandemic strain of coronavirus is unproven. While a paper published in Science Immunology attributed GM-CSF to be a key factor in COVID-19,

> additional clinical data may be needed to confirm the role of GM-CSF in patients with COVID-19. Certain additional data on the role of GM-CSF are also the subject of publications as well as pre-publication papers that have not been peer-reviewed and may not be substantiated. If this hypothesis is not ultimately proven through clinical trials which are underway, the potential for lenzilumab to play a meaningful role in a COVID-19 therapy likely would decrease or be eliminated. We cannot assure you that our exploratory efforts in this respect will be fruitful.

(emphasis in original)

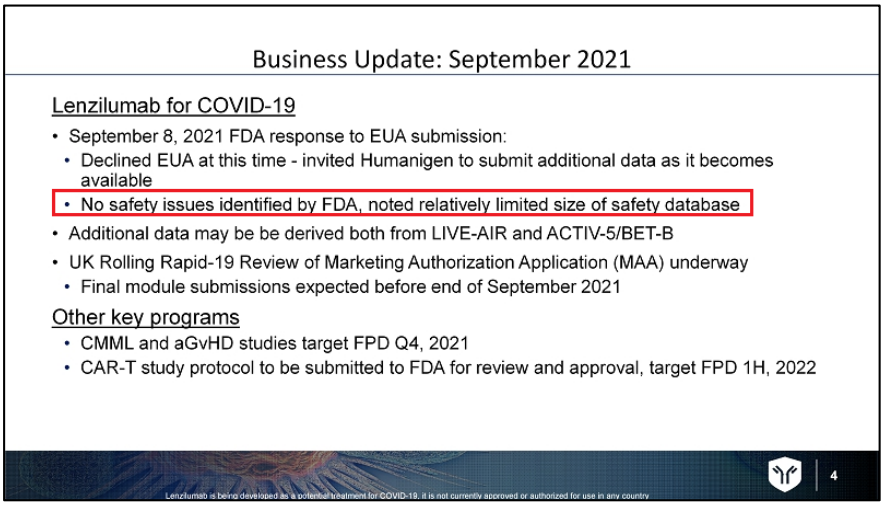
121. The above statements were false and/or materially misleading. A substantial amount of academic and medical literature already concluded that GM-CSF was vital for healthy lung function and, therefore, squarely contradicted the "hypothesis" that lenzilumab could be used as a COVID treatment. Notwithstanding, Humanigen told investors that "pre-publication papers" supported the "hypothesis" without saying anything about the negative data. The above statement falsely represented that negative data did not exist and/or the only data that did exist was positive and supportive with respect to lenzilumab's use for COVID treatment, which was not true. This prevented investors from understanding the true risks that existed concerning whether Humanigen's "hypothesis" would be ultimately proven and, in turn, the likelihood that lenzilumab would receive FDA-approval for treatment in COVID patients.

**September 14, 2021**

122. On September 14, 2021, after market hours, Humanigen filed a Form 8-K with the SEC attaching an investor presentation that, according to the Form 8-K,

would be used during upcoming investor conferences. Durrant signed the Form 8-K on behalf of Humanigen.

123. The investor presentation contained the following slide:




124. The statements identified in the above slide were false and/or materially misleading. The FDA rejected Humanigen's EUA application for lenzilumab because it was not supported by enough safety data. Given the FDA's decision along with the fact that GM-CSF played a critical role in healthy lung activity, Humanigen materially misrepresented lenzilumab's safety profile when it said "[n]o safety issues identified by FDA." This statement falsely described lenzilumab to be safer than it truly was and concealed material adverse information about the drug's prospects for regulatory approval.

**October 5, 2021**

125. On October 5, 2021, Humanigen participated in the Guggenheim Vaccine and Infectious Disease Conference. Chappell presented on behalf of

Humanigen.

126. During his opening remarks, Chappell stated as follows:

> So just in terms of some updates, as many may be aware, on September 8, the FDA declined our Emergency Use Authorization submission. Essentially, the FDA asked for more clinical data. ***Just to be very clear, there was no identification of any safety issues with lenzilumab***. So the FDA invited us to submit more data when it was available and continue the process of developing lenzilumab under an EUA for COVID-19, which we plan to do, and we will get into some of how we plan to supply that additional data.

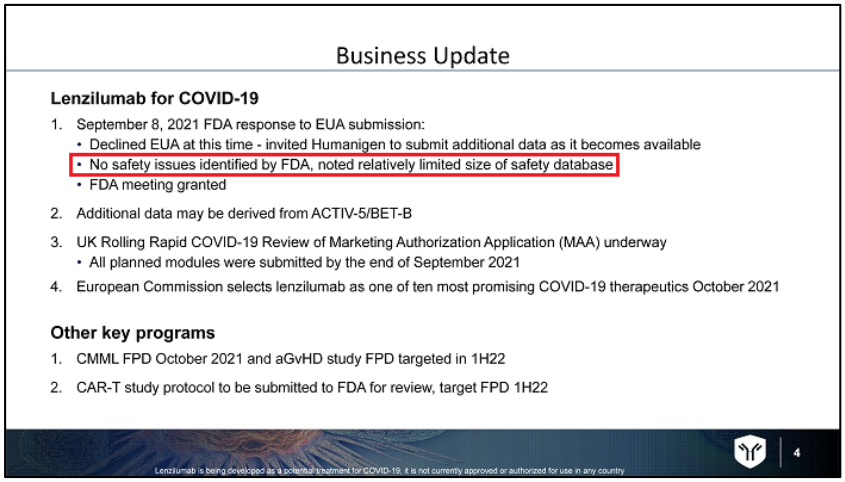
(emphasis added)

127. The statements identified in the above slide were false and/or materially misleading. The FDA rejected Humanigen's EUA application for lenzilumab because it was not supported by enough safety data. Given the FDA's decision along with the fact that GM-CSF played a critical role in healthy lung activity, Chappell materially misrepresented lenzilumab's safety profile when he said "there was no identification of any safety issues with lenzilumab." This statement falsely described lenzilumab to be safer than it truly was and concealed material adverse information about the drug's prospects for regulatory approval.

**November 9, 2021**

128. On November 9, 2021, Humanigen filed a report on Form 8-K with the SEC, along with an exhibit entitled "Credit Suisse Healthcare Conference Presentation." Durrant signed the Form 8-K on behalf of Humanigen.

129. The presentation contained the following slide:

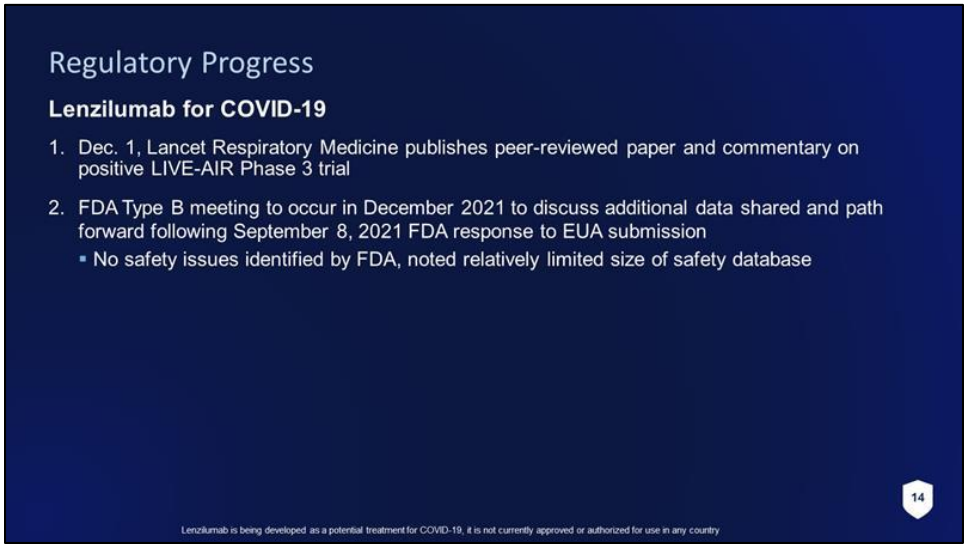



130. The statements identified in the above slide were false and/or materially misleading. The FDA rejected Humanigen's EUA application for lenzilumab because it was not supported by enough safety data. Given the FDA's decision along with the fact that GM-CSF played a critical role in healthy lung activity, Humanigen materially misrepresented lenzilumab's safety profile when it said "[n]o safety issues identified by FDA." This statement falsely described lenzilumab to be safer than it truly was and concealed material adverse information about the drug's prospects for regulatory approval.

**December 2, 2021**

131. On December 2, 2021, Humanigen filed a copy of an investor presentation with the SEC attached to a Form 8-K. Durrant signed the Form 8-K on behalf of Humanigen.

132. The presentation included the following slide:




133. The statements identified in the above slide were false and/or materially misleading. The FDA rejected Humanigen's EUA application for lenzilumab because it was not supported by enough safety data. Given the FDA's decision along with the fact that GM-CSF played a critical role in healthy lung activity, Humanigen materially misrepresented lenzilumab's safety profile when it said "[n]o safety issues identified by FDA." This statement falsely described lenzilumab to be safer than it truly was and concealed material adverse information about the drug's prospects for regulatory approval.

**February 28, 2022**

134. On February 28, 2022, after market hours, Humanigen filed an annual report on Form 10-K with the SEC for fiscal 2021. Durrant and Chappell signed the annual report on behalf of Humanigen.

135. The annual report stated that Humanigen was developing lenzilumab as

a treatment for COVID patients and purported to provide investors with the scientific rationale for doing so. In pertinent part, the annual report stated as follows:

> Following the emergence of the SARS-CoV-2 virus that leads to the condition referred to as COVID-19, scientific literature suggested that GM-CSF is critical for the initiation of the hyperinflammatory cascade experienced by many hospitalized patients characterized in the later and sometimes fatal stages by lung dysfunction and, in many patients, multi-organ impairment. Multiple publications have pointed to GM-CSF as being a signature cytokine in this process, with elevated GM-CSF levels correlated to poorer outcomes, including ventilator use, Intensive Care Unit ("ICU") admission, and mortality.
>
> . . .
>
> Data from National Scientific Review (2020, Vol. 7, No. 6) titled "Pathogenic T-cells and inflammatory monocytes incite inflammatory storms in severe COVID-19 patients", supports the hypothesis that GM-CSF induced cytokine storm immune mechanisms have contributed to patient mortality with the current pandemic strain. We believe that there is increasing acceptance that this pathophysiology may be responsible for worsening of clinical status and poor outcomes. The authors noted that steroid treatment in such cases has been disappointing in terms of outcome but suggested that a monoclonal antibody that targets GM-CSF may prevent or curb the hyper-active immune response caused by COVID-19 in this setting. Several publications point to GM-CSF as a so-called 'signature cytokine' including the largest inflammatory marker study in over 600 patients from a multicenter study in the UK. . . . .
>
> . . .
>
> In response to the scientific literature, we designed and conducted a Phase 3 clinical trial of lenzilumab in newly hospitalized COVID-19 patients, which we refer to as the "LIVE-AIR" study, to examine whether lenzilumab's neutralization of human GM-CSF could prevent or reduce poor outcomes associated with COVID-19.
>
> . . .

> . . . Topline results from ACTIV-5/BET-B are expected to be released late in the first quarter or early in the second quarter of 2022. If confirmatory of the results of the findings of the CRP subgroup from the LIVE-AIR study, we plan to include the results from ACTIV-5/BET-B in an amendment to our EUA submission . . . .

136. The statements identified above were false and/or materially misleading. While Humanigen provided investors with the "scientific rationale" for using lenzilumab to treat COVID patients, it identified only positive support for the treatment while concealing the substantial amount of published academic and medical literature that had already concluded that GM-CSF played a vital role in healthy and normal lung function. This academic and medical literature materially contradicted Humanigen's "scientific rationale" for using lenzilumab to treat COVID patients and concealed the significant patient risks that lenzilumab posed to COVID patients. Thus, by describing only supportive literature without providing a description of the research and literature as a whole, Humanigen misled investors to believe that lenzilumab could be used as a COVID treatment without unreasonable risk and, in turn, provided investors with a materially misleading description of the regulatory risks Humanigen faced with respect to obtaining an EUA and/or BLA approval from the FDA.

**June 21, 2022**

137. On June 21, 2022, Humanigen presented at Lytham Partners' Summer Investor Conference in San Francisco, California. Chappell presented on behalf of

Humanigen. In response to analyst questions, Chappell stated in pertinent part as follows:

> *Joe Diaz Lytham Partners – Managing Partner*
>
> So how does your drug candidate, lenzilumab, work? And what implications does this have for its potential use in COVID-19 and potentially other indications?
>
> *Dale Chappell Humanigen, Inc. – Chief Scientific Officer*
>
> Yeah, Joe, let me just -- I think I skipped over the last part of your prior question on INV and death, so maybe I'll go back and address that, and then I'll jump to the mechanism of action of lenz. . . . .
>
> *Joe Diaz Lytham Partners – Managing Partner*
>
> Sure. So again, with regards to lenz, let's talk about its implications for COVID-19 and other possible indications.
>
> *Dale Chappell Humanigen, Inc. – Chief Scientific Officer*
>
> Yes, absolutely. So as we've talked about at the very beginning when we are introducing the company, lenzilumab neutralizes this inflammatory cytokine called GM-CSF. And when we think about GM-CSF, what does it actually do? It activates a specific part of the immune system called myeloid cells.
>
> Now, myeloid cells are very important for cytokine storm because they are the cytokine factories. If you want to think about them that way. And GM-CSF is really what drives myeloid cells. So it causes them to be hyper-stimulated and to secrete a lot of cytokines.
>
> So we talked about GM-CSF being an upstream driver, a cytokine storm. And you can see it here on the slide with the arrow pointing to this myeloid cell or the cytokine factory. It causes this cytokine factory to get ramped up. And then that cytokine factory produces a number of other inflammatory cytokines such as IL-1 and IL-6.

And that's what really then leads to what we think about as cytokine storm. And once we get this overproduction of these inflammatory cytokines, we can get in-organ damage. ***You can get a pulmonary damage, for example, or renal damage. And that's what we see in COVID-19.***

. . .

*Joe Diaz Lytham Partners – Managing Partner*

Yes. So as it relates to your expectation of data from the NIH ACTIV-5, which you're expecting really in next month or so. Assuming that data is positive, what would you imagine next step be to seek regulatory ability, to commercialize lenz for COVID-19? What's the next step?

*Dale Chappell Humanigen, Inc. – Chief Scientific Officer*

So our expectations are that within weeks of receiving that topline data from NIH, and I remember this is an NIH study, so that data will be coming from NIH. We plan to amend our emergency use authorization with FDA, followed shortly thereafter by a formal response to MHRA. Now, that's the UK regulatory authority. So we'll be filing that same data then with MHRA in the UK for a conditional marketing authorization.

In terms of our plans for the European Union and their regulatory authority, the EMA, again, we'll use that data package from ACTIV-5 and the ACTIV-5. So both data packages. And we'll be seeking a conditional marketing authorization there for the EMA, for the European Union. And we'll do that under a accelerated assessment process.

So with positive data, we think we can have regulatory authorizations and be potentially commercializing, assuming authorization, lenzilumab for hospitalized patients with COVID-19 this year. So this could be a very important year and a real value-inflection point for Humanigen from a late-stage biotech company to a true commercialization footprint.

(emphasis added)

138. The statements identified above were false and/or materially misleading.

Lenzilumab inhibited GM-CSF cytokines which were integral to normal lung functions, as academic literature and medical studies confirmed. Thus, lenzilumab presented material patient-safety risks if used to treat lung dysfunction in COVID patients. Chappell did not disclose this despite being asked twice to explain the "implications" of how lenzilumab "work[ed]" when being used to treat COVID patients. Instead, Chappell only disclosed the potential negative outcomes that could occur as a result of "cytokine storm," such as "pulmonary damage." By disclosing negative outcomes from "cytokine storm" while at the same time not disclosing the material information about lenzilumab's negative effect on normal lung function, Chappell precluded investors from properly evaluating the risks associated with the company's development program and prospects for regulatory approval, which Chappell told investors they thought they could obtain and begin "commercializing" within the year.

## ADDITIONAL SCIENTER ALLEGATIONS

### Defendants Knew Their Statements Were False

139. Defendants possessed material adverse information or, in the alternative, had access to material adverse information that contradicted their statements to the public. Consequently, when making the alleged false statements, they acted with scienter.

140. At all relevant times, lenzilumab was Humanigen's lead drug candidate.

Humanigen's business plan relied almost exclusively on the success of lenzilumab. This was true prior to COVID while the company was pursuing its "development program" as a CAR-T therapy as well as after COVID when Humanigen repurposed lenzilumab as a treatment for COVID-related lung dysfunction.

141. Following Humanigen's restructuring, lenzilumab became all the more important for Defendants because it represented the only viable pathway towards generating revenue. Humanigen repeatedly told investors in its filings with the SEC that it was at risk of not "generat[ing] sufficient revenue to continue [its] business" if it was "unable to develop, or obtain regulatory approval for . . . [lenzilumab]."

142. Humanigen's need to develop and commercialize lenzilumab was paramount. As of December 31, 2019, the company had an accumulated deficit of $284.9 million. The following year, this deficit grew to $374.4 million as of December 31, 2020, and increased further to $611.1 million as of December 31, 2021. By the end of the Class Period, Humanigen's accumulated deficit had reached $686.2 million (as of September 30, 2022).

143. In addition to its accumulated deficit, Humanigen financial status was made worse by the fact that it was not generating revenue. Humanigen had, in fact, "incurred net losses in nearly every year since [its] inception." Despite the bankruptcy and restructuring it underwent prior to the Class Period, Humanigen had consistently and at all relevant times expressed in its SEC filings a "going concern qualification,"

meaning that it Humanigen had "substantial doubt about [its] ability to continue as a going concern" because of its "net losses since inception," "negative operating cash flows," and the fact that its "total liabilities exceed[ed] total assets."

144. Humanigen was on the brink of insolvency. Despite this, the company invested significantly in lenzilumab in terms of time, money and resources. Humanigen incurred the majority of its research and development expenses on lenzilumab. Prior to COVID, lenzilumab constituted approximately 75% of Humanigen's overall research and development expenses; after COVID, it represented approximately 98% of the company's research and development expenses.

145. The increase in Humanigen's research and development expenses was due to expenses for lenzilumab from the LIVE-AIR clinical trial and the ACTIV-5/BET study. Consequently, even though Humanigen had substantial doubts about its ability to remain a going concern, it was pursuing lenzilumab in hopes of securing an EUA and/or BLA so it could commercialize the drug and generate revenue.

146. Analysts recognized that lenzilumab was of paramount importance to Humanigen and the main driver behind its value. For example, on August 13, 2021, H.C. Wainwright & Co. stated that: "We reiterate our Buy rating and $36 target. Our valuation is based on our clinical net present value (NPV)… [and] ... is currently based on the two lead opportunities for lenzilumab: (1) COVID-19 ***(69%***

***contribution)***; and (2) CART-T therapy (31% contribution)" (emphasis added).

147. The critical importance lenzilumab played in Humanigen's overall operations supports the conclusion that the Individual Defendants were familiar with lenzilumab's "development program" for use in COVID patients and either knew or had access to the complete record of academic literature and medical studies concerning GM-CSF and COVID lung dysfunction, including (i) the "[r]ecent data from China" and "pre-publication titled 'Aberrant pathogenic GM-CSF+ T cells and inflammatory CD14+CD16+ monocytes in severe pulmonary syndrome patients of a new coronavirus,'" as described in Humanigen's filings with the SEC as well as (ii) the papers and studies demonstrating that lenzilumab posed a serious safety risk for patients with lung dysfunction because inhibition of GM-CSF interfered with alveoli and lung homeostasis.

148. Defendants acted with scienter by disclosing positive literature in support of lenzilumab's use in COVID patients while concealing negative literature that would have revealed material patient-safety risks associated with using lenzilumab in COVID patients.

**Defendants Waged a Reckless Gamble**

149. Defendants knew or recklessly disregarded that Humanigen's patient-safety data was insufficient to support FDA-approval under either an EUA or BLA approval process. Notwithstanding, they proceeded with the approval process in

hopes of securing an unlikely yet profitable decision that would allow Humanigen to commercialize lenzilumab.

150. Almost immediately after COVID erupted, Humanigen initiated a "development program" for lenzilumab as a COVID treatment. Indeed, on March 13, 2020, the U.S. declared a national emergency for COVID. On March 16, 2020, with the filing of its annual report for fiscal 2019, Humanigen announced it was "exploring the potential for use of lenzilumab to prevent the emergence of [cytokine storm] in COVID [patients]." On March 20, 2020, Humanigen announced it had already started planning a Phase III study for COVID treatment. And by May 6, 2020, Humanigen had already dosed its first patient in what would later be known as its LIVE-AIR clinical trial.

151. On June 30, 2020, the FDA adopted guidance outlining the FDA's recommendations regarding the data needed to support approval for COVID treatments, titled *Development and Licensure of Vaccines to Prevent COVID-19*. The purpose of the guidance was, in part, to "provide an overview of key considerations to satisfy regulatory requirements" when developing COVID treatments.

152. With respect to clinical trials and trial populations in particular, the FDA said that "[s]ponsors should collect and evaluate at least preliminary clinical safety and immunogenicity data for each dose level and age group (e.g., younger versus older adults) to support progression of clinical development to include larger numbers

(e.g., ***hundreds***) of participants and participants at higher risk of severe COVID-19" (emphasis added).

153. In addition, the FDA warned that, "[t]o generate sufficient data to meet the BLA approval standard, late phase clinical trials to demonstrate vaccine efficacy with formal hypothesis testing ***will likely need to enroll many thousands of participants***, including many with medical comorbidities for trials seeking to assess protection against severe COVID-19" and that "[i]nitiation of late phase trials should be preceded by adequate characterization of safety and immunogenicity (e.g., ***in a few hundred participants for each vaccine candidate, dose level, and age group to be evaluated***) to support general safety, potential for vaccine efficacy, and low risk of vaccine-associated ERD" (emphasis added).

154. Defendants were aware of and had reviewed the FDA's June 2020 guidance, as demonstrated by the fact that Humanigen referenced it several times in its filings with the SEC in 2020 and 2021.

155. Humanigen did not have enough trial participants and, in turn, safety data to meet FDA-approval requirements. By October 2, 2020, when Humanigen had its first Type B meeting with the FDA, it had enrolled less than 300 patients in the LIVE-AIR study. This was insufficient to support approval, according to the FDA's June 2020 guidance.

156. Humanigen proceeded with its LIVE-AIR study notwithstanding. On

November 6, 2020, the company announced "positive interim Phase 3 data" that, according to Chappell, "significantly de-risked" the trial and supported the "addition of patients" from approximately 300 patients to 515 patients. Chappell stated further that the interim data continued to support Humanigen's plans for EUA and/or BLA approval and would provide an additional interim analysis once the study enrolled "approximately 390 patients."

157. On December 31, 2020, Humanigen provided an "update" concerning its LIVE-AIR trial. In a Form 8-K filed with the SEC after market hours, Humanigen stated in pertinent part that an additional "interim analysis for safety" had been conducted by the study's independent data safety monitoring board and that, based on "feedback from FDA regulators regarding the amount of patient data that would be required to support [a BLA]," Humanigen had "decided not to conduct an interim analysis for efficacy."

158. Defendants knew or recklessly disregarded that the LIVE-AIR trial did not provide enough data to support the EUA and/or a subsequent BLA. Humanigen employed Medical Science Liaisons to educate doctors in the field about lenzilumab and its potential to treat COVID patients. According to two former Medical Science Liaisons for Humanigen, the Medical Science Liaison team would meet regularly with executives at Humanigen to update them about the conversations they were having with doctors in the field.

159. The first Medical Science Liaison ("CW1") worked for Humanigen from June 2021 to January 2022. CW1 was employed by Humanigen through a third-party named Eversana. CW1 reported to Marc Bernarducci at Eversana who, in turn, reported to Omar Ahmed who served as Humanigen's SVP, Clinical, Medical and Scientific Affairs. The second Medical Science Liaison ("CW2") worked for Humanigen from August 2021 to January 2022. CW2 similarly reported to Bernarducci.

160. According to CW1, CW1 and other members of the Medical Science Liaison team met regularly (monthly and, at times, more often) with executives at Humanigen, including Omar Ahmed (SVP, Clinical, Medical and Scientific Affairs), Adrian Kilcoyne (Chief Medical Officer), and Ed Jordan (Chief Commercial Officer). The Medical Science Liaison team presented using PowerPoint presentations, which were made available to other Humanigen executives. CW2 similarly recalled the attendees of the meetings between the Medical Science Liaison team and Humanigen, naming Ahmed, Kilcoyne, and Jordan.

161. CW1 recalled that during these meetings the Medical Science Liaison team reported to Humanigen's executives that doctors in the field were requesting more safety and efficacy data than the LIVE-AIR study provided before they would embrace the drug as a treatment for COVID. CW1 recalled hearing this comment from a number of doctors in the field and that they did not believe the LIVE-AIR data

was robust enough to make a decision. Consequently, when the FDA rejected Humanigen's EUA application, CW1 was not surprised.

162. Notwithstanding the foregoing, on May 17, 2021, Defendants created the outward appearance that they had been complying with the FDA's guidance, as evidenced by an email sent by Durrant to Plaintiff Dr. Greenbaum. The email attached a link to the FDA's May 2021 guidance titled, *COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention*. The May 2021 guidance stated explicitly that it was "intended to complement other COVID-19 guidance" and then included a reference to the June 2020 guidance discussed above, *i.e.*, *Development and Licensure of Vaccines to Prevent COVID-19*. The May 2021 guidance also emphasized that the "[c]ollection of safety data is important for novel drugs as well as repurposed drugs being evaluated for COVID-19, ***as the safety profile of repurposed drugs may differ in a new population***" (emphasis added).

163. Defendants' public statements also evidence a course of conduct intended to artificially inflate Humanigen's stock price, and maintain that artificial inflation throughout the Class Period. In addition to the alleged false and/or materially misleading statements, on June 16, 2021, Durrant sent Plaintiff Dr. Greenbaum another email in which he attached a positive analyst report from Jefferies. In pertinent part, Durrant highlighted the positive statements from the analyst report in his email to Dr. Greenbaum, as follows:

**From:** SCOTT GREENBAUM <[redacted]>
**Date:** June 16, 2021 at 4:30:25 PM EDT
**To:** Cameron Durrant <[redacted]>
**Subject: Re: Jefferies analyst report relative to Regeneron news**

Cameron,
Thanks so much for keeping me in the loop.
Best,
Scott

Sent from my iPhone

On Jun 16, 2021, at 4:21 PM, Cameron Durrant <[redacted]> wrote:

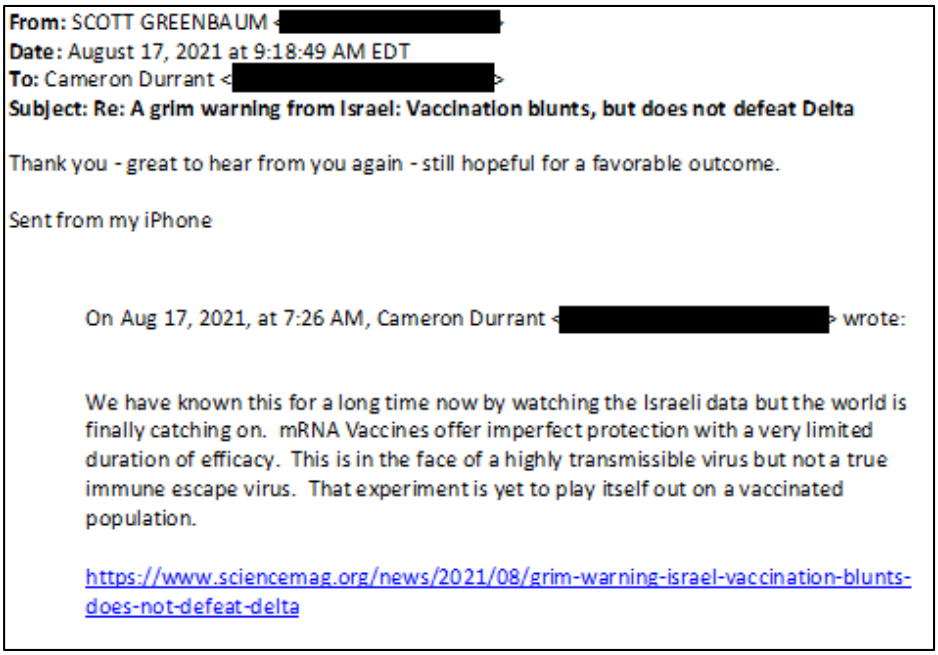
See quote:

**We think lenz showed superior survival benefit in all pts and even greater efficacy in sub-population.**

Interesting that a bank that also covers Regeneron, clearly a much bigger client than us, has our covering analyst make this statement.
Also amount of remdesivir used alongside the REGN cocktail not disclosed. We have heard UK use is in the 20% range. Interesting comment about potential synergy.

My take on REGN:
8g of protein!!!
No effect when sero neg and pos combined.
Open label.
REGN website PR second bullet is inaccurate – LIVE-AIR has that status…
Great spin.

164. Similarly, Durrant emailed Plaintiff Dr. Greenbaum again approximately two months later to highlight negative news in the world's efforts to develop a vaccination, thereby reiterating the relevance and need for treatments such as lenzilumab. On August 17, 2021, Durrant emailed Plaintiff Dr. Greenbaum a news report concerning Israel's vaccination program and provided negative commentary concerning mRNA vaccinations, stating in pertinent part as follows:



**From:** SCOTT GREENBAUM <[redacted]>
**Date:** August 17, 2021 at 9:18:49 AM EDT
**To:** Cameron Durrant <[redacted]>
**Subject: Re: A grim warning from Israel: Vaccination blunts, but does not defeat Delta**

Thank you - great to hear from you again - still hopeful for a favorable outcome.

Sent from my iPhone

On Aug 17, 2021, at 7:26 AM, Cameron Durrant <[redacted]> wrote:

We have known this for a long time now by watching the Israeli data but the world is finally catching on. mRNA Vaccines offer imperfect protection with a very limited duration of efficacy. This is in the face of a highly transmissible virus but not a true immune escape virus. That experiment is yet to play itself out on a vaccinated population.

https://www.sciencemag.org/news/2021/08/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

165. The patient safety risks created by lenzilumab in COVID patients presented a need for safety data that could only be achieved with a large, high-powered trial. The LIVE-AIR trial was not large enough but Defendants proceeded anyway in hopes of securing an EUA and, in turn, additional funding. With COVID raging across the country and around the world, Defendants engaged in a reckless gamble in hopes of obtaining approval under favorable albeit temporary circumstances, *i.e.*, the need for a COVID treatment.

166. Defendants' conduct in this regard was driven by Humanigen's dire financial condition and the limited window of opportunity they faced as a result of competitor development programs. As early as May 15, 2020, Humanigen admitted in its SEC filings that: "If our competitors develop and receive FDA approval for treatments or vaccines for COVID-19, ***our commercial opportunity will be reduced***

***or eliminated***. . . . If we are not the first therapy approved, or if other competing therapies are approved after lenzilumab, and/or a preventative vaccine is approved, such approval could have a ***material adverse impact on our ability to commercialize lenzilumab as a therapy for COVID-19***" (emphasis added).

**Humanigen Benefitted Financially from the Fraud**

167. Humanigen immediately began raising money off the news that it had decided to commence a "development program" for lenzilumab as a COVID treatment, notwithstanding that Defendants knew lenzilumab posed a serious safety risk in COVID patients with lung dysfunction and that the company's clinical trials were inadequate to support EUA and/or BLA approval.

168. Humanigen raised the following money from shareholders while in possession of material adverse non-public information:

a. On June 1, 2020, Humanigen sold 82.5 million shares in a private placement at a purchase price of $0.87 per share for aggregate gross proceeds of approximately $71.8 million;

b. On September 18, 2020, Humanigen held a public offering in connection with its uplisting to the NASDAQ. In total, Humanigen sold 9.2 million shares for aggregate gross proceeds of approximately $78.2 million;

c. On April 5, 2021, Humanigen held a public offering selling 5.4 million shares for aggregate gross proceeds of approximately $100.4 million;

d. During the nine-month period ended September 30, 2021, Humanigen raised an additional $40 million through an at-the-market sales offering occurring just prior to the company's EUA submission before the FDA rejected it; and

e. During the quarter ended March 31, 2022, Humanigen raised an additional $18.4 million through additional at-the-market sales, which amounted to just over 25% of its cash and cash equivalents at the time.

169. These capital raises were vital to Humanigen's ability to continue as a going concern. As of May 14, 2020, Humanigen's cash and cash equivalents were approximately $313 thousand. Absent the June 2020 private placement, Humanigen would not have been able to continue operations. Moreover, Humanigen's operating expenses in 2020 and 2021 were $88.5 million and $236.3 million, respectively. As of March 31, 2022, Humanigen once again had disclosed a "going concern" qualification in its quarterly report filed on Form 10-Q. Thus, without the cash generated from these sales, Humanigen would have ceased to exist.

## Chappell Realized Personal Financial Benefits from the Fraud

170. Chappell loaned millions of dollars to Humanigen through the Black Horse Entities that he controlled, received stock in exchange for those loans, and then sold that stock while in possession of material non-public information to recover his money. Chappell had a significant interest in recouping the funds he invested in Humanigen and, consequently, an extraordinary personal incentive to maintain the stock at an artificially inflated price.

### (a) Chappell Loaned Money to Humanigen Prior to the Class Period.

171. On December 21, 2016, the Black Horse Entities and Humanigen entered into a Credit and Security Agreement whereby the Black Horse Entities

provided Humanigen a credit facility in the original principal amount of $3,315,217.

172. On March 21, 2017, the Black Horse Entities and Humanigen amended the credit facility to provide Humanigen with an additional loan of $5,978,260, bringing the total amount borrowed to $9,293,477.

173. On July 8, 2017, the Black Horse Entities and Humanigen amended the credit facility again. Humanigen described the amendment in a Form 8-K as follows:

> The Second Amendment provides for additional loans that may be drawn by the Company on a bi-monthly basis from time to time (the "Grid Advances") in an aggregate principal amount of up to $5,434,783, less an upfront fee equal to 8% of each Grid Advance (the "Upfront Fee") due and payable at the time of each such advance. The Second Amendment requires the payment at maturity by the Company to the Lenders of a commitment fee equal to 5% of the aggregate amount of Grid Advances made, after deduction of the Upfront Fees (the "Commitment Fee"). Assuming the entire principal amount of Grid Advances were borrowed the total principal amount of the Term Loan outstanding would be $14,728,260.

174. On November 16, 2017, the Black Horse Entities and Humanigen amended the credit facility again to provide Humanigen with an extension. By this point, the total amount owed under the credit facility was approximately $16.1 million. The amendment also allowed for Humanigen to repay the loan with equity in the company. Humanigen described the extension in a Form 8-K as follows: "The Company does not have access to sufficient funds to repay the outstanding obligations under the Credit Agreement. Accordingly, the Company has been discussing and continues to discuss with its Lenders alternative transactions that might result in the

satisfaction of the Company's obligations, including the possible conversion of the term loans into equity of the Company, which might occur at a significant discount to current market prices and be dilutive to the ownership interests of existing stockholders."

**(b) Chappell Gained Control of Humanigen in February 2018.**

175. On December 27, 2017, Humanigen filed a Form 8-K (the "December 2017 8-K") with the SEC, signed by Defendant Durrant. The December 2017 8-K states that "[o]n December 1, 2017, the Company's obligation matured under the Credit Agreement. As of December 21, 2017, the aggregate amount of the Company's obligations under the Credit Agreement, including accrued interest and fees, approximated $16.3 million." "[T]he Company did not have access to sufficient funds to repay the Term Loans that [ ] matured and was in default under the Credit Agreement due to its failure to repay the Company's outstanding obligations[.]"

176. The December 2017 8-K further states that "[o]n December 21, 2017, the Company reached an agreement, unanimously approved by the Company's board of directors (the "Board"), with [Nomis and the Black Horse Entities] on a series of transactions providing for, among other things, the conversion of the Term Loans into common stock of the Company, par value $ 0.001 (the "Common Stock"), in satisfaction and extinguishment of the outstanding obligations under the Credit Agreement and the cancellation of the Term Loans." Humanigen had "entered into

definitive agreements with its lenders to, [ ] exchange the entire balance of approximately $16.3 million in term loans for common stock of the company." "Humanigen w[ould] also receive a new $3 million investment from an affiliate of Black Horse Capital, one of the lenders [Cheval], to fund the company and its transformational new strategy of developing the monoclonal antibodies lenzilumab.…"

177. On February 28, 2018, Humanigen filed a Form 8-K (the "February 2018 8-K) with the SEC, signed by Defendant Durrant. The February 2018 8-K states, that "[o]n December 21, 2017, Humanigen … entered into a Securities Purchase and Loan Satisfaction Agreement (the "Purchase Agreement") and a Forbearance and Loan Modification Agreement (together with the Purchase Agreement, the "Restructuring Agreements"), each with [Nomis and the Black Horse Entities], in connection with a series of transactions (collectively, the "Transactions"), providing for, among other things, the satisfaction and extinguishment of the Company's outstanding obligations under the Credit and Security Agreement[.]"

178. The February 2018 8-K states that the restructuring "transactions were completed on February 27, 2018[11] (the "Effective Date")[.]" The same Form 8-K further states, that:

> On the Effective Date, the Company: (i) in exchange for the satisfaction and extinguishment of all of the Company's approximately $16.7 million of

[11] On February 27, 2018, the Company's common stock was trading at $3.25 per share.

> outstanding obligations under the Credit Agreement, (a) issued to Lenders an aggregate of 59,786,848 shares of the Company's common stock (the "New Lender Shares"), with Nomis Bay and the Black Horse Entities each receiving 50% of the New Lender Shares; and … (ii) issued to Cheval an additional 32,028,669 shares of the Company's common stock (the "New Black Horse Shares" and, collectively with the New Lender Shares, the "New Common Shares") for total cash consideration of $3 million, $1.5 million of which the Company received on December 22, 2017 in the form of a bridge loan.

179. On October 28, 2019, Humanigen filed a Form 10-Q with the SEC, signed by Durrant. With respect to Humanigen's comprehensive restructuring, the Form 10-Q states, in relevant part (emphasis added):

> Upon completion of the Restructuring Transactions, the Black Horse Entities collectively held 66,870,851 shares of our common stock, or approximately 62.6% of our outstanding common stock. Accordingly, ***the completion of the Restructuring*** Transactions ***resulted in a change in control of our company, as the Black Horse Entities and their affiliates owning more than a majority of our outstanding common stock***. ***Dr. Dale Chappell***, a member of our board of directors from June 30, 2016 until November 10, 2017, ***controls the Black Horse Entities and accordingly, will be able to exert control over matters of our company and will be able to determine all matters of our company requiring stockholder approval***.

180. The completion of Humanigen's February 2018 Restructuring Transaction resulted in Chappell's status as the Company's controlling stockholder; a status held by Chappell until on or about June 2, 2020, when the Company entered into a private placement transaction in which the Company issued and sold additional shares at a discounted price.

**(c) Chappell Was the Largest Shareholder During the Class Period through his Control of the Black Horse Entities.**

181. As explained in a Form 8-K filed with the SEC on June 4, 2020 (the

"June 2020 8-K"), "[a]s a result of the completion of the Private Placement, the shares over which Dr. Chappell shares voting and dispositive power now comprise approximately 33.3% of the number of shares of Common Stock outstanding, and Dr. Chappell is no longer the controlling stockholder of the company." However, ***Chappell continued to be the Company's largest stockholder, and remained as such throughout the Class Period***.

182. On April 23, 2021, Humanigen filed a Schedule 14A Proxy Statement with the SEC. The April 2021 Proxy Statement indicated that Chappell was Humanigen's largest shareholder, beneficially owning 13,948,584 shares of Humanigen common stock or approximately 23.8% of the outstanding shares "based on information reported on Amendment No. 4 to the Schedule 13D/A filed with the SEC on September 22, 2020" (immediately before the start of the Class Period) "reporting beneficial ownership by the Black Horse Entities …, BH Management, and Dale Chappell." It further stated (emphasis added):

> According to the report, Black Horse Capital LP ("BHC") has sole voting and dispositive power with respect to 1,199,342 shares, Black Horse Capital Master Fund Ltd. ("BHCMF") has shared voting and dispositive power with respect to 2,799,566 shares, Cheval Holdings, Ltd. ("Cheval" and collectively with BHCMF and BHC, the "Black Horse Entities") has shared voting and dispositive power with respect to 9,927,383 shares, BH Management has sole voting and dispositive power with respect to 11,126,725 shares and ***Dr. Chappell has shared voting and dispositive power with respect to 13,926,291 shares***. The number of shares reported for Dr. Chappell also includes options to purchase 22,293 shares of common stock that may be exercised within 60 days of April 16, 2021.

183. Chappell's interest in recouping the funds loaned to the Company through the Black Horse Entities constitutes an unusual circumstance, and in part, supports his motive to commit fraud. Chappell's incentive to maintain a high stock price goes beyond the Company's ordinary goals and directly to his own financial gain.

**(d) Chappell Traded Humanigen Stock While in Possession of Material, Non-Public Information.**

184. As a result of the aforementioned loans to the Company and the satisfaction and extinguishment of such loans, Defendant Chappell was the beneficial owner of a significant amount of Humanigen common stock, a great deal of which was sold for millions of dollars in proceeds during the Class Period. The sales occurred from June 2021 through August 2021, at which time Chappell knew there was an increased risk that Humanigen's EUA application filed in May 2021 would be denied because of the patient safety risk lenzilumab presented as an anti-GM-CSF in persons with lung dysfunction as well as the FDA's June 2020 guidance requiring larger patient populations than the LIVE-AIR trial.

185. On June 4, 2021, a Form 4 was filed jointly by Defendant Chappell, "Black Horse Capital LP (the 'Domestic Fund')," "Black Horse Capital Master Fund Ltd. (the 'Offshore Fund')", "Cheval Holdings, Ltd. ('Cheval')", and "Black Horse Capital Management LLC ('BH Management')", (collectively, the "Reporting Persons"), indicating that between June 2, 2021 and June 4, 2021, the Reporting

Persons sold 394,364 shares of Humanigen common stock at prices varying between approximately $18.37 and $19.01 per share and that: (a) 62,276 of these "[s]ecurities [were] owned directly by the Domestic Fund. BH Management, as the managing general partner of the Domestic Fund, may be deemed to beneficially own the securities owned directly by the Domestic Fund. ***Dale Chappell, as the managing member of BH Management, may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 124,553 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell, as the controlling person of the Offshore Fund, may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 207,535 of these "[s]ecurities [were] owned directly by Cheval. Each of BH Management, by virtue of having been granted by the Board of Directors of Cheval the power to manage the securities of [Humanigen] owned by Cheval, and ***Dale Chappell, as the managing member of BH Management, may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added)

186. On June 9, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that on June 7, 2021, the Reporting Persons sold another 80,636 shares of Humanigen common stock at approximately $19.08 per share, and that: (a) 12,732 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 25,464 of these "[s]ecurities

[were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 42,440 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

187. On June 21, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that between June 16, 2021 and June 18, 2021, the Reporting Persons sold another 742,389 shares of Humanigen common stock at prices varying between approximately $18.50 and $19.50 per share, and that: (a) 56,523 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 151,211 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 534,655 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***"

188. From June 23, 2021 through August 2021, Chappell continued to sell Humanigen common stock while in possession of material, non-public information. While the sales reported during this period were purportedly effected pursuant to a trading plan adopted pursuant to Rule 10b5-1 under the Exchange Act, the plan is not

exculpatory because it appears to have been adopted ***after*** the beginning of the Class Period, while Chappell was in possession of the alleged material, non-public information.

189. On June 25, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that between June 23, 2021 and June 25, 2021, the Reporting Persons sold another 1,272,655 shares of Humanigen common stock at prices varying between approximately $17.80 and $18.37 per share, and that: (a) 95,450 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 254,531 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 922,674 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

190. On July 2, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that between June 30, 2021 and July 2, 2021, the Reporting Persons sold another 363,096 shares of Humanigen common stock at prices varying between approximately $17.10 and $17.28 per share, and that: (a) 34,733 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale***

***Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 92,618 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 235,745 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

191. On July 9, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that between July 8, 2021 and July 9, 2021, the Reporting Persons sold another 344,046 shares of Humanigen common stock at prices varying between approximately $17.17 and $17.37 per share, and that: (a) 25,804 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 68,809 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 249,433 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

192. On July 16, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that on July 14, 2021, the Reporting Persons sold another 15,177 shares of Humanigen common stock at

approximately $17.06 per share, and that: (a) 1,138 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 3,036 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 11,003 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

193. On July 23, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that on July 14, 2021, the Reporting Persons sold another 316,353 shares of Humanigen common stock at prices varying between approximately $17.04 to $17.14 per share and that: (a) 23,726 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 63,271 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 229,356 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

194. On July 30, 2021, the same Reporting Persons (which included

Defendant Chappell) filed a Form 4 with the SEC indicating that on July 14, 2021, the Reporting Persons sold another 39,086 shares of Humanigen common stock at prices varying between approximately $17.03 to 17.04 per share, and that: (a) 2,931 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 7,817 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 28,338 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell … may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

195. On August 13, 2021, the same Reporting Persons (which included Defendant Chappell) filed a Form 4 with the SEC indicating that between August 11, 2021 and August 12, 2021, the Reporting Persons sold another 167,198 shares of Humanigen common stock at prices varying between approximately $17.07 to $17.16 per share, and that: (a) 12,540 of these "[s]ecurities [were] owned directly by the Domestic Fund…. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Domestic Fund.***"; (b) 33,439 of these "[s]ecurities [were] owned directly by the Offshore Fund. ***Dale Chappell … may be deemed to beneficially own the securities owned directly by the Offshore Fund.***"; and (c) 121,219 of these "[s]ecurities [were] owned directly by Cheval…. ***Dale Chappell …***

***may be deemed to beneficially own the securities owned by Cheval.***" (Emphasis added.)

196. The following table summarizes the above stock sales made by or on behalf of Chappel:

| **Date of Sales** | **Amount** | **Price/Share** | **Proceeds** |
|---|---|---|---|
| Jun. 2-4, 2021 | 394,364 | $18.37-$19.01 | $7,304,994 |
| Jun. 7, 2021 | 80,636 | $19.08 | $1,538,793 |
| Jun. 16-18, 2021 | 742,389 | $18.50-$19.50 | $14,000,187 |
| Jun. 23-25, 2021 | 1,272,655 | $17.80-$18.37 | $22,801,511 |
| Jun. 30-Jul. 2, 2021 | 463,096 | $17.10-$17.28 | $7,959,379 |
| Jul. 8-Jul. 9, 2021 | 344,046 | $17.17-$17.37 | $5,966,879 |
| Jul. 14, 2021 | 15,177 | $17.06 | $258,847 |
| Jul. 14, 2021 | 316,353 | $17.04-$17.14 | $5,403,075 |
| Jul. 14, 2021 | 39,086 | $17.03-$17.04 | $665,866 |
| Aug. 11-12, 2021 | 167,198 | $17.07-$17.16 | $2,859,709 |
| ***Total:*** | ***3,835,000*** | ***Total:*** | ***$68,759,240*** |

197. By selling the above shares during the Class Period, Chappell avoided millions of dollars in losses. Specifically, had Chappell waited until the end of the Class Period to sell these shares, he would have realized proceeds of less than $2.4 million (*i.e.*, based on the post-Class Period stock price of $0.61 per share on July 13, 2022). Thus, by engaging in the above intra-Class Period sales, Chappell realized over ***$66 million*** in proceeds that he otherwise would not have been able to secure.

198. In addition, these sales are indicative of scienter because they are suspicious in timing and amount relative to Chappel's previous and subsequent trading patterns. Chappell had not sold any Humanigen shares prior to the Class Period and, in fact, did not sell any shares of Humanigen after the Class Period. Thus,

his intra-Class Period sales represent the only known sales of Humanigen stock to date.

**Durrant Realized Personal Financial Benefits from the Fraud**

199. Durrant loaned money to Humanigen, received stock in exchange for those loans and then sold that stock while in possession of material non-public information to recover his money. Durrant had a significant interest in recouping the funds he invested in Humanigen and, consequently, an extraordinary personal incentive to maintain the stock at an artificially inflated price.

**(a) Durrant Loaned Money to Humanigen in Exchange for Stock.**

200. Defendant Durrant loaned $100,000 to the Company, and in satisfaction and extinguishment of such loans, received 235,624 shares of the Company's common stock. On May 31, 2019, Defendant Durrant filed a Form 4 with the SEC, reporting that 235,624 "shares of common stock were issued to Dr. Durrant in full satisfaction of two $50,000 loans made to the Company in June and August 2018, respectively, including accrued and unpaid interest thereon, in accordance with the terms of the promissory notes delivered by the Company to evidence the loans."

201. As a result, Durrant had a significant interest in recouping the funds loaned to the Company, and an extraordinary personal incentive to maintain the stock at an artificially inflated price.

**(b) Durrant Traded Humanigen Stock While in Possession of Material, Non-Public Information.**

202. On June 16, 2021, Durrant filed a Form 4 with the SEC reporting that the Cameron Durrant Revocable Trust, of which he and his spouse are trustees and his spouse is the primary beneficiary, sold an aggregate of 81,441 shares of Humanigen's common stock on June 14, 2021 at $20.60 to $21.14 per share. The sales occurred while Durrant was in possession of material, non-public information.

203. By selling the above shares during the Class Period, Durrant avoided approximately $1.6 million in losses. Specifically, had Durrant waited until the end of the Class Period to sell these shares, he would have realized proceeds of approximately $81,500 (*i.e.*, based on the post-Class Period stock price of $0.61 per share on July 13, 2022). Thus, by engaging in the above intra-Class Period sales, Chappell realized over $1.6 million in proceeds that he otherwise would not have been able to secure.

204. In addition, these sales are indicative of scienter because they are suspicious in timing and amount relative to Durrant's previous and subsequent trading patterns. Durrant's sale is the only sale of Humanigen that he made, according to SEC filings. Thus, his intra-Class Period sales represent the only known sales of Humanigen stock to date.

## LOSS CAUSATION AND ECONOMIC HARM

205. Throughout the Class Period, Defendants made materially misleading

statements and omissions, which artificially inflated the price of Humanigen's securities and operated as a fraud or deceit on Class Period purchasers of these securities. These misleading statements and omissions provided investors with false information and concealed material risks. As these risks materialized and the truth began to emerge, the prior artificial inflation came out of Humanigen's stock price and Plaintiffs and other members of the Class suffered foreseeable economic losses, which were proximately caused by Defendants materially misleading the investing public.

206. The market for Humanigen's stock was open, well-developed and efficient at all relevant times. Defendants' misrepresentations and omissions created a false impression in the market as to the viability of lenzilumab as a COVID treatment, the overall clinical benefit of the drug, Humanigen's ability to secure approval under an EUA and/or BLA, and its ability to commercialize lenzilumab. In turn, this caused Humanigen's shares to be overvalued and artificially inflated during the Class Period.

207. Reasonably relying on the integrity of the market price for Humanigen's securities and market information relating to lenzilumab, Plaintiffs and other members of the Class purchased or otherwise acquired Humanigen's securities to their detriment as they sustained damages in response to the revelation of corrective information, as discussed below.

208. On September 8, 2021, Humanigen issued a press release stating, in pertinent part, that: "FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19." The press release also quoted Durrant who stated, in pertinent part, that: "We believe the ongoing ACTIV-5/BET-B trial, which has been advanced to enroll up to 500 patients, may provide additional safety and efficacy data sufficient to support our efforts to obtain an EUA to treat hospitalized COVID-19 patients."

209. Humanigen's disclosure on September 8, 2021, prompted an immediate decline in the price of its stock, as investors began to question lenzilumab and whether data would ultimately demonstrate a clinical benefit for use in COVID patients, as Defendants previously represented. On this news, Humanigen's stock price fell $7.14 per share, or 47.25%, from $15.11 per share to close at $7.97 per share on September 9, 2021. Despite this decline in Humanigen's stock price, Humanigen securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding lenzilumab's clinical and commercial prospects.

210. On July 12, 2022, Humanigen issued another press release stating, in pertinent part, that it "has been informed of preliminary topline results from the National Institute of Allergy and Infectious Diseases' (NIAID) ACTIV-5/BET-B trial

evaluating lenzilumab plus remdesivir versus placebo plus remdesivir in hospitalized COVID-19 patients. The trial did not achieve statistical significance on the primary endpoint, which was defined as the proportion of patients with baseline CRP<150 mg/L and age<85 years, alive and without mechanical ventilation through Day 29. The data also showed a non-significant trend toward a reduction in mortality in the overall patient population [HR 0.72]. There were no new safety signals attributed to lenzilumab in the ACTIV-5/BET-B study."

211. The press release also included a quote from Durrant, stating that: "We are grateful for the constructive collaboration with NIH/NIAID; while the ACTIV-5/BET-B study showed signs of a clinical effect, the benefit demonstrated was not able to confirm the positive results we saw in our Phase 3 LIVE-AIR study. . . . In order to prove the therapeutic benefits of immunomodulators, platform studies comprising thousands of patients have been necessary. With the continued resurgence of COVID-19, further exploration of variant agnostic treatments to improve outcomes in hospitalized COVID-19 patients should be a priority."

212. The information concerning the ACTIV-5/BET-B study starkly contrasted with Defendants' previous statements about lenzilumab's ability to be used as a treatment in COVID patients and that the data to date demonstrated a clinical benefit. To the contrary, it became clear to investors that lenzilumab required a significant amount of additional patient safety data in order to demonstrate a clinical

benefit and, in turn, substantiate an EUA and/or BLA application. Humanigen's disclosure operated as a correction to Defendants' previous false and/or materially misleading statements and omissions during the Class Period and/or a distinct materialization of risks that were concealed by Defendants during the Class Period.

213. As the market promptly digested the gravity of this disclosure, it resulted in an immediate, dramatic decline in Humanigen's stock price. Between July 12, 2022 and July 13, 2022, Humanigen's stock price plunged from $2.99 per share to $0.61 per share, representing a decline of $2.38 per share or 79.6%. Humanigen's stock has never recovered. It presently trades below $0.20 per share and is at risk of being delisted from the Nasdaq.

214. Throughout the Class Period, Defendants withheld information that was material to the market's assessment of lenzilumab and its potential for commercialization. Specifically, Defendants withheld material information concerning safety risks about lenzilumab's application in COVID patients and Humanigen's ability to demonstrate a clinical benefit. This, in turn, resulted in investors being deceived as to Humanigen's ability to secure an EUA and/or BLA and commercialize lenzilumab.

215. To the contrary, Defendants touted literature that supported the "scientific rationale" behind using lenzilumab to treat COVID patients along with "positive" study data while simultaneously concealing serious risks and safety issues,

which Defendants knew or had reason to know. These dangerous risks severely diminished Humanigen's chances of successfully demonstrating a clinical benefit for lenzilumab's use in COVID patients and commercializing the drug. Investors who purchased Humanigen's securities during the Class Period were deceived as to these risks and the full impact they would have on Humanigen's business until these very risks materialized through the disclosures detailed above.

216. Defendants' misrepresentations and omissions were the foreseeable, proximate cause of Plaintiffs' and Class Members' damages because the risk that caused the loss was within the zone of risk concealed by the misrepresentations and omissions alleged by Plaintiffs. Inherent in Defendants' misrepresentations and omissions was the foreseeable consequence that any revelation of truth or materialization of concealed risks would lead to a precipitous decline in the value of Humanigen's shares thereby causing significant economic losses to Plaintiffs and other Class Members.

217. Defendants' wrongful conduct alleged herein was the direct and proximate cause of the economic losses suffered by Plaintiffs and other members of the Class. During the Class Period, Plaintiffs and other Class Members purchased Humanigen's stock at prices that were artificially inflated by Defendants' materially misleading statements and omissions, and when Defendants' misleading statements were corrected and/or the information alleged herein to have been concealed from the

market was revealed, the price of Humanigen's stock significantly declined, causing Plaintiffs' and Class Members' losses.

## NO SAFE HARBOR

218. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged herein. Many of the statements alleged were not identified as "forward-looking" when made, and, to the extent any statements were forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

219. Alternatively, to the extent that the statutory safe harbor applies to any forward-looking statements alleged, Defendants are liable for such statements because, at the time they were made, the speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Humanigen who knew that those statements were false when made.

## CLASS ACTION ALLEGATIONS

220. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Humanigen securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures.

Excluded from the Class are Defendants herein, the officers and directors of Humanigen, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

221. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Humanigen securities were actively traded on the OTCQB and/or NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Humanigen or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

222. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

223. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

224. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Humanigen;

c. whether the Individual Defendants caused Humanigen to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Humanigen securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

225. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

226. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. Humanigen securities are traded in an efficient market;

d. Humanigen's shares were liquid and traded with moderate to heavy volume during the Class Period;

e. Humanigen traded on the OTCQB and/or NASDAQ and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of Humanigen's securities; and

g. Plaintiffs and members of the Class purchased, acquired and/or sold Humanigen securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

227. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

228. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

## COUNT I

## Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

229. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

230. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

231. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Humanigen securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Humanigen securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan

and course of conduct, Defendants, and each of them, took the actions set forth herein.

232. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Humanigen securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Humanigen's finances and business prospects.

233. By virtue of their positions at Humanigen, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

234. Information showing that Defendants acted knowingly or with reckless

disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Humanigen, the Individual Defendants had knowledge of the details of Humanigen's internal affairs.

235. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Humanigen. As officers and/or directors of a publicly- held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Humanigen's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Humanigen securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Humanigen's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Humanigen securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

236. During the Class Period, Humanigen securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the

materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Humanigen securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Humanigen securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Humanigen securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

237. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

238. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of Humanigen's securities during the Class Period, upon the disclosure that it had been disseminating misrepresented financial statements to the investing public.

## COUNT II

## Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

239. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

240. The Individual Defendants possessed the power and authority to control the contents of Humanigen's SEC filings, press releases, and other market communications. They were provided with copies of Humanigen's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Humanigen, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

241. As officers, directors, and/or controlling shareholders of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Humanigen's operations and to correct promptly any public statements issued by Humanigen which had become materially false or misleading.

242. Because of their positions of control and authority as senior officers, directors, or controlling shareholders, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Humanigen disseminated in the marketplace during the Class Period concerning Humanigen's operations. During the Class Period, the Individual Defendants exercised their power and authority to cause Humanigen to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Humanigen within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Humanigen securities.

243. Each of the Individual Defendants, therefore, acted as a controlling person of Humanigen. By reason of their senior management positions, role as directors of Humanigen, or controlling shareholders, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Humanigen to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Humanigen and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

244. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by

Humanigen.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

## DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

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Dated: March 27, 2023

Respectfully submitted,

LEVI & KORSINSKY, LLP

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